FT PharmaSuite®

EBR PHASES
RELEASE 11.01.00
FUNCTIONAL REQUIREMENT SPECIFICATION

Rockwell Automation

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FT PharmaSuite® 11.01.00 - Functional Requirement Specification EBR Phases

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1 Introduction

This document details the requirements of the functions implemented by the phases specific to EBR. The phases are executed in the Production Execution Client of PharmaSuite.

Each requirement is composed of a name (e.g., Preview mode) and a unique identifier (e.g., GID-1234567) and is extended with its business attributes (GxP Relevance, Business Impact) and its compliance attribute (21 CFR Part 11 Relevance).

For requirements with **Framework capability** as identifier, see "Functional Requirement Specification Execution Framework" for their unique identifier, [A1] (GID-2667978).

The revision history lists the changes made to the document with the previous FactoryTalk PharmaSuite release as the comparison baseline. It provides individual tables for "Updated", "Added", and "Deleted" requirements that juxtapose the previous approved version with the new approved version of an item.

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface	Designates user interface texts, such as ▪ window and dialog titles ▪ menu functions ▪ panel, tab, and button names ▪ box labels ▪ object properties and their values (e.g., status).
Monospaced typeface	Designates code examples.

FT PharmaSuite® 11.01.00 - Functional Requirement Specification EBR Phases
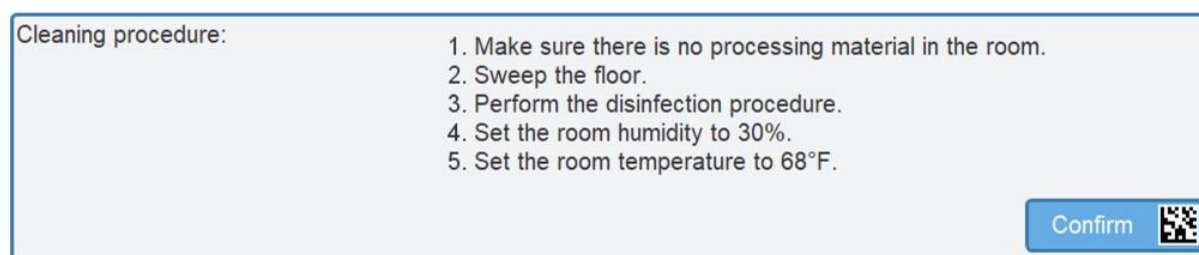
2 Show Instruction Text (SR0030+)

The **Show instruction text** phase allows to display a specific instruction related to the process step the operator is executing.

Example use cases are:

- Description of how to assemble equipment.
- Description of how to sample the product.
- Information about specifics of a process activity.

The instruction text is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669220).

Figure 1: Show instruction text during execution

2.1 Layout

(GID-2669219)The phase provides individual layouts for its representation during execution (GID-2669218), in the Navigator link, and in the sub-report (GID-2669220).

2.1.1 Representation during Execution (SR0030.1+)

The representation during execution depends on the phase mode.

2.1.1.1 GID-2670987 PREVIEW MODE (SR0030.1.2)

1. <Instruction text> (column 1, column 2, and column 3)
   (taken from **Instruction (SR0030.8.1)** process parameter (GID-2670999)and the **Layout (SR0030.8.2)** process parameter (GID-2671000))

2. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.1.2 GID-2670988 ACTIVE MODE (SR0030.1.1)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text> (column 1, column 2, and column 3)
   (taken from **Instruction (SR0030.8.1)** process parameter (GID-2670999)and the **Layout (SR0030.8.2)** process parameter (GID-2671000))

3. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.1.3 GID-2670989 COMPLETED MODE (SR0030.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text> (column 1, column 2, and column 3)
   (taken from **Instruction (SR0030.8.1)** process parameter (GID-2670999)and the **Layout (SR0030.8.2)** process parameter (GID-2671000))

3. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.2 Representation in Navigator (SR0030.4+)

The Navigator provides the following details:

2.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Mix inputs

2.1.2.2 GID-2670991 INFORMATION COLUMN (SR0030.4.1)

- <Empty>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

2.1.3 Representation in Sub-report (SR0030.5+)

The sub-report contains the following information:

2.1.3.1 COMMON SUB-REPORT ELEMENTS ()

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

2.1.3.2 GID-2670994 SUB-REPORT ELEMENTS (SR0030.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Up to three instruction texts

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.2 Business Logic (SR0030.2+)

The phase implements the following business logic.

2.2.1 GID-2669221 Display instruction text (SR0030.2.1)

- Function: Display an instruction text

- Trigger: Phase becomes active

- Postcondition: Instruction text was displayed

Step	#	Description
Phase activation	10	Phase displays instruction text.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3 Process Parameters (SR0030.8+)

The following process parameters define the behavior of the phase.

2.3.1 Instruction Table-specific Parameters

2.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

2.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

2.3.2 Instruction Link-specific Parameters

2.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2670998). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

2.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

2.3.3 Basic Parameters

2.3.3.1 GID-2670999 INSTRUCTION (SR0030.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags). The layout settings define which columns will be visible (see **Type** attribute of the **Layout (SR0030.8.2)** process parameter (GID-2671000)).
Column 2	HTML text	
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.3.2 GID-2671000 LAYOUT (SR0030.8.2)

Attribute	Type	Comment
Type	Choice list	Defines the layout of the column(s) holding the instruction texts: **1** column, **2** columns (with narrow first column and wide second column), **2** columns (with wide first column and narrow second column), or **3** columns). Default setting: **1 column.**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.4 Exceptions

The phase supports user-defined, user-triggered (GID-2669226), system-triggered (GID-2669225), and post-completion exceptions (GID-2669227)and their configuration by means of process parameters (GID-2667909).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

2.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

2.4.2 User-triggered Exceptions

There are no user-triggered exceptions available.

2.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

2.5 Information Messages

There are no information messages available.

2.6 Questions

There are no questions available.

2.7 Decisions

There are no decisions available.

2.8 Error Messages

There are no error messages available.

2.9 Output Variables

The following output variables are available to reference the phase's output.

2.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

2.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

2.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

2.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

3 Show Document (SR0040+)

The **Show document** phase allows to display a variety of documents.

Example use cases are:

- Display an SOP
  An SOP is stored within a central DMS. This very SOP can be displayed to the operator during execution.

- Show an instruction video
  The instruction of a GMP-critical process step is available as a video. The video can be shown during execution.

The name of the work instruction (document) and the instruction text are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669234).

The name of the displayed document is shown on the detail information button in the Navigator (e.g. SOP).

Read the instructions for manual mixing.

Work instruction: M1492

Open   Confirm
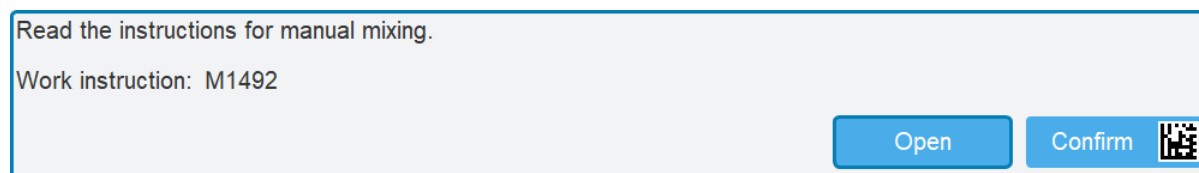
Figure 2: Show document during execution

PHARMA AT ITS BEST INC.	SOP Manual Mixing Procedure	M1492
		Page: 1 of 1
		Version: 2.4
		Valid from: 10-Nov-2012

Perform all of the steps as described:

1. Sterilize surface.
2. Place inputs in mixing vessel.
3. Stir for 15 minutes.
4. Cover the mixture.
5. Leave it stand for 10 minutes.
6. Stir until smooth.
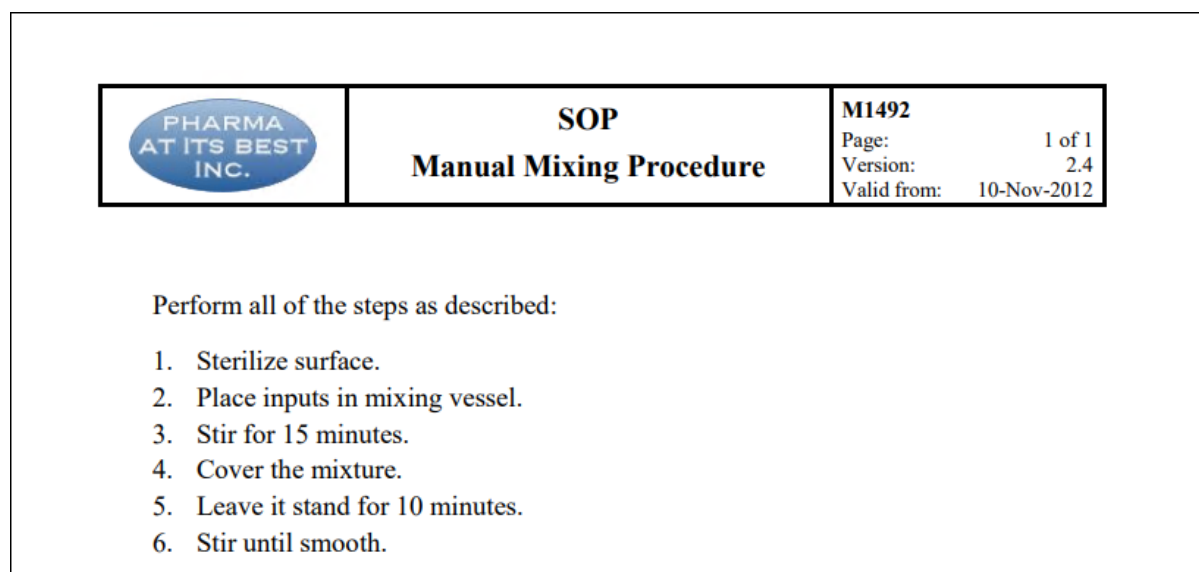
Figure 3: Show document during execution

3.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669232), in the Navigator (GID-2669233), and in the sub-report (GID-2669234).

3.1.1 Representation during Execution (SR0040.1+)

The representation during execution depends on the phase mode.

3.1.1.1 GID-2671001 PREVIEW MODE (SR0040.1.2)

1. <Instruction text>
   (taken from **Instruction (SR0040.8.1)** process parameter (GID-2671013))

2. Work instruction: <name of the work instruction>
   (taken from **Document (SR0040.8.2)** process parameter (GID-2671014))

3. **Open** button (disabled).

4. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.2 GID-2671002 ACTIVE MODE (SR0040.1.1)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0040.8.1)** process parameter (GID-2671013))

3. Work instruction: <name of the work instruction>
   (taken from **Document (SR0040.8.2)** process parameter (GID-2671014))

4. **Open** button.

5. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.1.3 GID-2671003 COMPLETED MODE (SR0040.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0040.8.1)** process parameter (GID-2671013))

3. Work instruction: <name of the work instruction>
   (taken from **Document (SR0040.8.2)** process parameter (GID-2671014))

4. **Open** button (disabled).

5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.2 Representation in Navigator (SR0040.4+)

The Navigator provides the following details:

3.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Mix inputs

3.1.2.2 GID-2671005 INFORMATION COLUMN (SR0040.4.1)

- <Name of the work instruction>

  - Example: SOP

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

3.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

3.1.3 Representation in Sub-report (SR0040.5+)

The sub-report contains the following information:

3.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

3.1.3.2 GID-2671008 SUB-REPORT ELEMENTS (SR0040.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Work instruction: <name of the work instruction>

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.2 Business Logic (SR0040.2+)

The phase implements the following business logic.

3.2.1 GID-2669235 Display document (SR0040.2.1)

- Function: Display a document

- Trigger: Open button pressed

- Postcondition: Document was displayed

Step	#	Description
Open button pressed	10	Phase opens and displays the document with the application registered at operating system for the work instruction file type.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3 Process Parameters (SR0040.8+)

The following process parameters define the behavior of the phase.

3.3.1 Instruction Table-specific Parameters

3.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

3.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

3.3.2 Instruction Link-specific Parameters

3.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671012). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

3.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

3.3.3 Basic Parameters

3.3.3.1 GID-2671013 INSTRUCTION (SR0040.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.3.3.2 GID-2671014 DOCUMENT (SR0040.8.2)

Attribute	Type	Comment
Work instruction	Text	Name of a FactoryTalk ProductionCentre work instruction object. The Production Execution Client will show the document with the application registered at operating system for the work instruction file type. The Work Instruction Selection editor is a **Framework capability**. Maximum length is 64 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3.4 Exceptions

The phase supports user-defined, user-triggered (GID-2669240), system-triggered (GID-2669239), and post-completion exceptions (GID-2669241) and their configuration by means of process parameters (GID-2667919).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

3.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

3.4.2 User-triggered Exceptions

There are no user-triggered exceptions available.

3.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

3.5 Information Messages

There are no information messages available.

3.6 Questions

There are no questions available.

3.7 Decisions

There are no decisions available.

3.8 Error Messages

There are no error messages available.

3.9 Output Variables

The following output variables are available to reference the phase's output.

3.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

3.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

3.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

3.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

4 Upload Image Phase (SR0090+)

(GID-2667940)The **Upload image** phase allows an operator to upload an image to document processing-related information.

Example use cases are:

- Recording of visual appearance during product test
  During the inspection of a product sample, a picture of the sample can be taken and uploaded.

- Supporting the operator with graphical instructions
  When the operator starts a specific processing step, the phase automatically displays the required illustration.

The phase supports the following file formats: JPG, GIF, and PNG.

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Selection** mode, the operator manually selects an image file to be uploaded.

- In the **Loading** mode, the operator triggers the upload of an already pre-defined image file.

- In the **Automatic loading** mode, the phase loads a pre-defined image file automatically.

- In the **Automatic completion** mode, the phase loads a pre-defined image file and is completed automatically without any operator interaction.

The uploaded image and its meta data are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669271).
Anomalies that occur during processing are covered by the phase exception handling (GID-2667940)(e.g. required image has not been uploaded).

After completion the phase displays the uploaded image in the Execution Window. The Navigator displays the file name of the uploaded image and provides access to the post-completion exception.
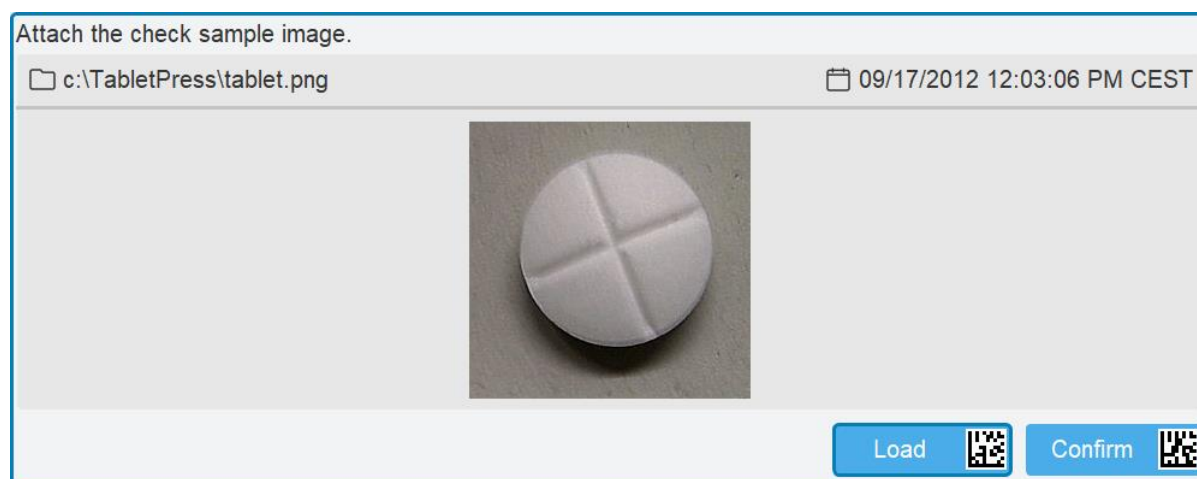
Figure 4: Upload image during execution - Automatic loading mode
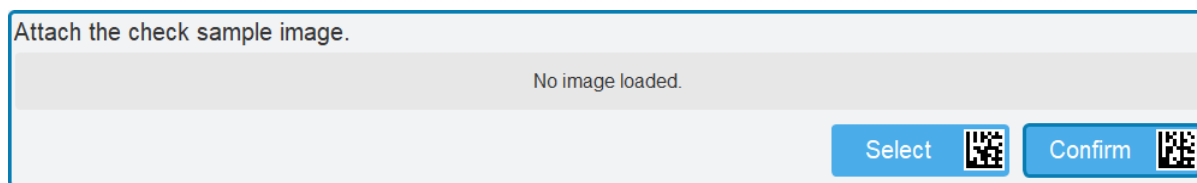
Figure 5: Upload image during execution - Automatic loading mode

4.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669269), in the Navigator (GID-2669270), and in the sub-report (GID-2669271).

4.1.1 Representation during Execution (SR0090.1+)

The representation during execution depends on the phase mode.

4.1.1.1 GID-2671042 PREVIEW MODE (SR0090.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0090.8.1)** process parameter (GID-2671061))

2. Depends on **Mode (SR0090.8.2)** process parameter (GID-2671062):

   - In **Selection** mode: **Select** button (disabled)

   - In all other modes than **Selection**: **Load** button (disabled)

3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.2 GID-2671043 ACTIVE MODE (SR0090.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction ((GID-2671061))** process parameter link)

3. Depends on **Mode (SR0090.8.2)** process parameter (GID-2671062):

   - In **Selection** mode: **Select** button to open file selection dialog

   - In all other modes than **Selection**: **Load** button to load pre-defined image

4. <Full path name of image file>
   <Modification time of image file>
   Uploaded image.

5. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.1.3 GID-2671044 COMPLETED MODE (SR0090.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0090.8.1)** process parameter (GID-2671061))

3. <Full path name of image file>
   <Modification time of image file>
   Uploaded image.

4. **Load** / **Select** button (disabled). **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.2 Representation in Navigator (SR0090.4+)

The Navigator provides the following details:

4.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Mixer AB_3X

4.1.2.2 GID-2671046 INFORMATION COLUMN (SR0090.4.1)

- Image file name or N/A if no image has been uploaded

  - Example: IMG001.JPG

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.2.3 GID-2671047 ACTION COLUMN (SR0090.4.2)

- Replace file, provides exception to replace the uploaded image by a manual file selection.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

4.1.3 Representation in Sub-report (SR0090.5+)

The sub-report contains the following information:

4.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- \<Start time\>

- \<Completion time\>

- \<Unit procedure\> / \<operation\> / \<phase\>

- \<Work center\> / \<station\> / \<device\> - \<phase completion user\>

4.1.3.2 GID-2671049 SUB-REPORT ELEMENTS (SR0090.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Image loaded at: \<work center identifier\>

- Image loaded from: \<Full path name of image file\>

- Image modified on: \<Modification time of image file\>

- Uploaded image

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2 Business Logic (SR0090.2+)

The phase implements the following business logic.

4.2.1 Phase Mode

Business logic related to phase modes.

4.2.1.1 GID-2671050 Selection mode (SR0090.2.1)

- Function: **Selection** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0090.1.2)** layout (GID-2671043).
Operator action	20	The **Select** button opens a file selection dialog, see **Select image (SR0090.2.2)** function (GID-2671054).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.2 GID-2671051 Loading mode (SR0090.2.4)

- Function: **Loading (pre-defined file)** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0090.1.2)** layout (GID-2671043).
Operator action	20	The **Load** button loads an image file, see **Load image (SR0090.2.5)** function (GID-2671055).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.3 GID-2671052 AUTOMATIC LOADING MODE (SR0090.2.6)

- Function: **Automatic loading (pre-defined file)** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0090.1.2)** layout (GID-2671043).
Phase loads image file	20	Phase loads the image automatically according to the settings of the **File location (SR0090.8.3)** process parameter (GID-2671063). If one of the following issues occurs, phase displays an error message: ▪ Image cannot be loaded, **Load image error (SR0090.3.6.1)** error message (GID-2669284). ▪ Image cannot be displayed, **Display image error (SR0090.3.6.2)** error message (GID-2669285). ▪ Image cannot be determined, **Image ambiguous (SR0090.3.6.3)** error message (GID-2669286). When the error message has been confirmed, phase returns to the **Active mode (SR0090.1.2)** layout (GID-2671043). Otherwise continue with step 40.
Operator interaction	30	In case the automated upload results in an error, the operator can still trigger the upload of an image file manually with the **Load** button, see **Load image (SR0090.2.5)** function (GID-2671055). The same checks apply as for step 20.
Phase displays image	40	Phase displays the image in the image placeholder of the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1.4 GID-2671053 AUTOMATIC COMPLETION MODE (SR0090.2.7)

- Function: **Automatic completion (pre-defined file)** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0090.1.2)** layout (GID-2671043).
	20	Phase loads the image automatically according to the settings of the **File location (SR0090.8.3)** process parameter (GID-2671063). If one of the following issues occurs, phase displays an error message: ▪ Image cannot be loaded, **Load image error (SR0090.3.6.1)** error message (GID-2669284). > ▪ Image cannot be displayed, **Display image error (SR0090.3.6.2)** error message (GID-2669285). ▪ Image cannot be determined, **Image ambiguous (SR0090.3.6.3)** error message (GID-2669286). When the error message has been confirmed, phase returns to the **Active mode (SR0090.1.2)** layout (GID-2671043). Otherwise continue with step 40.
Operator interaction	30	In case the automated upload results in an error, the operator can still trigger the upload of an image file manually with the **Load** button, see **Load image (SR0090.2.5)** function (GID-2671055). The same checks apply as for step 20. The phase needs to be completed manually by the operator.
Phase displays image	40	Phase displays the image in the image placeholder of the phase.
	50	Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.2 Main Path

Business logic related to the main path:

4.2.2.1 GID-2671054 SELECT IMAGE (SR0090.2.2)

- Function: Image selection and loading

- Type: Main path

- Trigger: Operator opens file selection dialog

- Postcondition: Phase is active

Step	#	Description
Operator opens file selection dialog	10	Phase displays the file selection dialog. Starting directory is taken from the **File location (SR0090.8.3)** process parameter (GID-2671063).
	20	The displayed images are filtered using the configured wildcards (* = multiple characters or ? = single character) for the file name. The file name is taken from the **File location (SR0090.8.3)** process parameter (GID-2671063).
Operator selects an image file	30	Phase closes the file selection dialog.
Phase displays image	40	Phase displays the image in the image placeholder of the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.2.2 GID-2671055 LOAD IMAGE (SR0090.2.5)

- Function: Image loading

- Type: Main path

- Trigger: Operator loads an image file

- Postcondition: Phase is active

Step	#	Description
Operator loads an image file	10	Phase loads the image according to the settings of the **File location (SR0090.8.3)** process parameter (GID-2671063). If one of the following issues occurs, phase displays an error message: ▪ Image cannot be loaded, **Load image error (SR0090.3.6.1)** error message (GID-2669284). ▪ Image cannot be displayed, **Display image error (SR0090.3.6.2)** error message (GID-2669285). ▪ Image cannot be determined, **Image ambiguous (SR0090.3.6.3)** error message (GID-2669286). When the error message has been confirmed, phase returns to the **Active mode (SR0090.1.2)** layout (GID-2671043). Otherwise continue with step 20.
Phase displays image	20	Phase displays the image in the image placeholder of the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.2.3 GID-2671056 Confirm phase (SR0090.2.3)

▪ Function: Completion of phase

▪ Type: Main path

▪ Trigger: Operator confirms phase

▪ Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	Operator confirms uploaded image.
Phase checks setting of **Mandatory upload check (SR0090.8.6)** process parameter (GID-2671064)	20	If **Mandatory upload check** is enabled: ▪ If no image has been uploaded, phase creates the **Mandatory upload check (SR0090.3.2.1)** system-triggered exception (GID-2671067). When the exception has been registered, phase returns to the **Active mode (SR0090.1.2)** layout (GID-2671043). ▪ If an image has been uploaded or the system-triggered exception has been registered, continue with step 30.

Step	#	Description
	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3 Process Parameters (SR0090.8+)

The following process parameters define the behavior of the phase.

4.3.1 Instruction Table-specific Parameters

4.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

4.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column.
Column 2	HTML text	**Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

4.3.2 Instruction Link-specific Parameters

4.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671060). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

4.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

4.3.3 Basic Parameters

4.3.3.1 GID-2671061 INSTRUCTION (SR0090.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.3.2 GID-2671062 MODE (SR0090.8.2)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Selection** (default): Operator selects an image file. **Loading (pre-defined file)**: Operator triggers phase to load a pre-defined image file. **Automatic loading (pre-defined file):** Phase automatically loads a pre-defined image file. **Automatic completion (pre-defined file):** Phase automatically loads a pre-defined image file and is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.4 Image Parameters

4.3.4.1 GID-2671063 FILE LOCATION (SR0090.8.3)

Attribute	Type	Comment
Directory path	Text	Defines the directory path of the image file to be loaded. Environment variables are supported (e.g. %USERNAME%). If the **Mode (SR0090.8.2)** process parameter (GID-2671062) is set to **Selection**, the specified path is the starting point for the file selection dialog. The operator can navigate to another directory.
File name	Text	Defines the name of the image file to be loaded. If the **Mode (SR0090.8.2)** process parameter (GID-2671062)is set to **Selection**, all image files are available for selection. If the **Mode (SR0090.8.2)** process parameter (GID-2671062)is **not** set to **Selection**, the file name must be unique even if wildcards are used.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.5 Configuration of System-triggered Exceptions

4.3.5.1 GID-2671064 MANDATORY UPLOAD CHECK (SR0090.8.6)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If not, the phase can be completed without an image upload. If so, the phase can only be completed with an image upload or if the **Mandatory upload check (SR0090.2.1)** system-triggered exception (GID-2671067)has been registered.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters. **Mandatory** if the **Enabled** attribute is set to **Yes.**

See also **Mandatory upload check (SR0090.3.2.1)** system-triggered exception (GID-2671067).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.6 Configuration of User-triggered Exceptions

4.3.6.1 GID-2671065 SELECT MANUALLY (SR0090.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Select manually (SR0090.3.1.1)** user-triggered exception (GID-2671069).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.7 Configuration of Post-completion Exceptions

4.3.7.1 GID-2671066 REPLACE FILE (SR0090.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

> See also **Replace file (SR0090.3.3.1)** post-completion exception (GID-2671071).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4 Exceptions (SR0090.3+)

The phase supports user-defined, user-triggered (GID-2669282), system-triggered (GID-2669281), and post-completion exceptions (GID-2669283)and their configuration by means of process parameters (GID-2667939).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

4.4.1 System-triggered Exceptions (SR0090.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

4.4.1.1 GID-2671067 MANDATORY UPLOAD CHECK (SR0090.3.2.1)

Representation of the exception:

- \<Exception text\>
  (taken from **Mandatory upload check (SR0090.8.6)** process parameter (GID-2671064)

  - Example:
    Mandatory upload of the sample kit picture is skipped.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4.1.2 GID-2671068 MANDATORY UPLOAD CHECK- LOGIC (SR0090.3.2.1.1)

- Trigger: Operator confirms phase

- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	Phase creates **Mandatory upload check (SR0090.3.2.1)** system-triggered exception.
Operator triggers exception	20	Phase records the exception.
Operator confirms exception	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4.2 User-triggered Exceptions (SR0090.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

4.4.2.1 GID-2671069 SELECT MANUALLY (SR0090.3.1.1)

The **Select manually** exception allows an operator to select an image file manually. The settings of the **Mode (SR0090.8.2)** process parameter (GID-2671062)are ignored. If an image has already been uploaded, the image is replaced.

Representation during exception handling:

- Instruction:
  To display another image, select its image file.
  Select button.
  <Old image>
  <Full path name of old image file>
  <Modification time of old image file>
  <New image>
  <Full path name of new image file>
  <Modification time of new image file>
  Confirm button.

- Exception text:

  <Exception text>

  (taken from **Select manually (SR0090.8.4)** process parameter <u>(GID-2671065))</u>

  Old image: <Full path name>, <Modification time>

  New image: <Full path name>, <Modification time>

  - Example:

    Manual selection

    Old image: C:\upload\IMG001.JPG, 08/03/2012 10:43:26 AM CEST

    New image: C:\upload\IMG002.JPG, 08/04/2012 10:43:26 AM CEST

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4.2.2 GID-2671070 SELECT MANUALLY - LOGIC (SR0090.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: Image is uploaded

Step	#	Description
Operator confirms exception	10	See **Select image (SR0090.2.2)** function <u>(GID-2671054)</u>.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4.3 Post-completion Exceptions (SR0090.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

4.4.3.1 GID-2671071 REPLACE FILE (SR0090.3.3.1)

The **Replace file** exception allows an operator to manually replace the uploaded image from the Navigator after the phase has been confirmed. If an image has already been uploaded, the image is replaced.

> **TIP**
>
> A recorded value could be used within branching. The correction of a value **does not influence** already processed branching decisions.

Representation of the exception:

- Instruction:
  To display another image, select its image file.
  Select button.
  \<Old image\>
  \<Full path name of old image file\>
  \<Modification time of old image file\>
  \<New image\>
  \<Full path name of new image file\>
  \<Modification time of new image file\>
  Confirm button.

- \<Exception text\>
  (taken from **Replace file (SR0090.8.6)** process parameter [(GID-2671064)](GID-2671064))
  Old image: \<Full path name\>, \<Modification time\>
  New image: \<Full path name\>, \<Modification time\>

  - Example:
    Image replaced (after phase completion).
    Old image: C:\upload\IMG001.JPG, 08/03/2012 10:43:26 AM CEST
    New image: C:\upload\IMG002.JPG, 08/04/2012 10:43:26 AM CEST

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.4.3.2 GID-2671072 REPLACE FILE - LOGIC (SR0090.3.3.1.1)

- Trigger: Phase is completed

- Postcondition: Post-completion exception is recorded

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
Operator confirms exception	30	See **Select image (SR0090.2.2)** function [(GID-2671054)](GID-2671054). The **Load** button is disabled.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.5 Information Messages

There are no information messages available.

4.6 Questions

There are no questions available.

4.7 Decisions

There are no decisions available.

4.8 Error Messages (SR0090.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

4.8.1 GID-2669284 Load image error (SR0090.3.6.1)

UI text	Comment
Cannot load the image, since the pre-defined file name (invalid file name) does not exist.	Message pack: PhaseBasicUploadImage<version> Message ID: ParamFileLocation_NoFileFound_ErrorMsg
Cannot load the image, since the pre-defined directory (<invalid directory>) does not exist.	Message pack: PhaseBasicUploadImage<version> Message ID: ParamFileLocation_DirDoesNotExist_ErrorMsg
Cannot load the image, since there is no directory path defined.	Message pack: PhaseBasicUploadImage<version> Message ID: ParamFileLocation_NoDirConfigured_ErrorMsg
Cannot load the image, since there is no file name defined.	Message pack: PhaseBasicUploadImage<version> Message ID: ParamFileLocation_NoFileConfigured_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.2 GID-2669285 Display image error (SR0090.3.6.2)

UI text	Comment
Cannot load the image file.	Message pack: PhaseBasicUploadImage<version> Message ID: LoadFile_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.8.3 GID-2669286 Image ambiguous (SR0090.3.6.3)

UI text	Comment
Cannot load the image, since the pre-defined file location contains more than one matching file.	Message pack: PhaseBasicUploadImage<version> Message ID: ParamFileLocation_FileAmbiguous_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.9 Output Variables (SR0090.9+)

The following output variables are available to reference the phase's output.

4.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

4.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

4.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

4.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

4.9.5 GID-2669291 Image full path (SR0090.9.4)

- Data type: String

- Usage: The output variable provides the full path and file name of the uploaded image.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.9.6 GID-2669292 Image timestamp (SR0090.9.5)

- Data type: Timestamp

- Usage: The output variable provides the modification time of the uploaded image.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.10 Configuration Keys (SR0090.11+)

The following configuration keys are available to configure the phase's behavior.

4.10.1 GID-2669293 Maximum file size (SR0090.11.1)

- **Phase/UploadImage/uploadMaximumFileSize**

- **Type**: Long

- **Value**: N/A

- **Description**: Defines the maximum allowed file size in bytes of the image file to be uploaded. Default: 1000000

- **Range**: <=1000000

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5   Upload PDF Phase (SR0100+)

The **Upload PDF** phase allows an operator to upload a PDF file, to display its content, and to document the content in the batch report.

Example use cases are:

- Attaching documentation to the batch report
  During execution, the operator can upload a PDF file that provides information about test results of a sample.

- Supporting the operator with instructions that need to be recorded in the batch report
  When the operator starts a specific processing step, the phase automatically uploads and displays the required PDF file.

> **TIP**
>
> If the content of a PDF file shall only be displayed, but not included in the batch report, use the **Show URL (SR0120+)** phase (GID-2667958).

Different phase modes enable the usage in various situations that can occur during processing:

- In the **Selection** mode, the operator manually selects a PDF file to be uploaded.

- In the **Loading** mode, the operator triggers the upload of an already pre-defined PDF file.

- In the **Automatic loading** mode, the phase loads a pre-defined PDF file automatically.

- In the **Automatic completion** mode, the phase loads a pre-defined PDF file and is completed automatically without any operator interaction.

The uploaded PDF file and its meta data are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669296).
Anomalies that occur during processing are covered by the phase exception handling (GID-2667951)(e.g. required PDF file has not been uploaded).

After completion the phase displays the file name of the uploaded PDF file in the Execution Window. The Navigator displays the file name of the uploaded PDF file and provides access to the post-completion exception.

Figure 6: Upload PDF during execution - Automatic loading mode

Figure 7: Upload PDF during execution - Automatic loading mode

5.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669294), in the Navigator (GID-2669295), and in the sub-report (GID-2669296).

5.1.1 Representation during Execution (SR0100.1+)

The representation during execution depends on the phase mode.

5.1.1.1 GID-2671073 PREVIEW MODE (SR0100.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0100.8.1)** process parameter (GID-2671092))

2. Depends on **Mode (SR0100.8.2)** process parameter (GID-2671093):

   - In **Selection** mode: **Select** button (disabled)

   - In all other modes than **Selection**: **Load** button (disabled)

3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.2 GID-2671074 ACTIVE MODE (SR0100.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0100.8.1)** process parameter (GID-2671092))

3. Depends on **Mode (SR0100.8.2)** process parameter (GID-2671093):

   - In **Selection** mode: **Select** button to open file selection dialog

   - In all other modes than **Selection**: **Load** button to load pre-defined PDF file

4. <Full path name of PDF file>
   <Modification time of PDF file>
   Content of uploaded PDF file.

5. Buttons to navigate through the uploaded PDF file (**First page**, **Previous page**, **Previous line**, **Next line**, **Next page**, **Last page**).

6. Page number of the currently displayed page and the total number of pages

7. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.1.3 GID-2671075 COMPLETED MODE (SR0100.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0100.8.1)** process parameter (GID-2671092))

3. <Full path name of PDF file>
   <Modification time of PDF file>
   Content of uploaded PDF file.

4. **Load** / **Select** button (disabled). **Confirm** button (completed).

5. Buttons to navigate through the uploaded PDF file (**First page**, **Previous page**, **Previous line**, **Next line**, **Next page**, **Last page**).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2 Representation in Navigator (SR0100.4+)

The Navigator provides the following details:

5.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    SOP: Mixer AB_3X

5.1.2.2 GID-2671077 INFORMATION COLUMN (SR0100.4.1)

- PDF file name or N/A if no PDF file has been uploaded

- Example: SOP001.PDF

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.2.3 GID-2671078 Action column (SR0100.4.2)

- Replace file, provides exception to replace the uploaded PDF file by a manual file selection.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

5.1.3 Representation in Sub-report (SR0100.5+)

The sub-report contains the following information:

5.1.3.1 Common sub-report elements (Framework capability)

- \<Start time>

- \<Completion time>

- \<Unit procedure> / \<operation> / \<phase>

- \<Work center> / \<station> / \<device> - \<phase completion user>

5.1.3.2 GID-2671080 Sub-report elements (SR0100.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- PDF loaded at: \<work center identifier>

- PDF loaded from: \<Full path name of PDF file>

- PDF modified on: \<Modification time of PDF file>

- Content of uploaded PDF file

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2 Business Logic (SR0100.2+)

The phase implements the following business logic.

5.2.1 Phase Mode

Business logic related to phase modes.

5.2.1.1 GID-2671081 SELECTION MODE (SR0100.2.1)

- Function: **Selection** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0100.1.2)** layout (GID-2671074).
Operator action	20	The **Select** button opens a file selection dialog, see **Select PDF (SR0100.2.2)** function (GID-2671085).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.1.2 GID-2671082 LOADING MODE (SR0100.2.4)

- Function: **Loading (pre-defined file)** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0100.1.2)** layout (GID-2671081).
Operator action	20	The **Load** button loads a PDF file, see **Load PDF (SR0100.2.5)** function (GID-2671086).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.1.3 GID-2671083 AUTOMATIC LOADING MODE (SR0100.2.6)

- Function: **Automatic loading (pre-defined file)** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays PDF file
Phase loads PDF file	20	Phase loads the PDF file automatically according to the settings of the **File location (SR0100.8.3)** process parameter (GID-2671094). If one of the following issues occurs, phase displays an error message: - PDF cannot be loaded, **Load PDF error (SR0100.3.6.1)** error message (GID-2669309) - PDF cannot be displayed, **Display PDF error (SR0100.3.6.2)** error message (GID-2669310). - PDF cannot be determined, **PDF ambiguous (SR0100.3.6.3)** error message (GID-2669311). When the error message has been confirmed, phase returns to the **Active mode (SR0100.1.2)** layout (GID-2671074). Otherwise continue with step 40.
Operator interaction	30	In case the automated upload results in an error, the operator can still trigger the upload of a PDF file manually with the **Load** button, see **Load PDF (SR0100.2.5)** function (GID-2671086). The same checks apply as for step 20.
Phase displays PDF file	40	Phase displays the PDF file in the PDF placeholder of the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.1.4 GID-2671084 AUTOMATIC COMPLETION MODE (SR0100.2.7)

- Function: **Automatic completion (pre-defined file)** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0100.1.2)** layout (GID-2671074).
	20	Phase loads the PDF file automatically according to the settings of the **File location (SR0100.8.3)** process parameter (GID-2671094). If one of the following issues occurs, phase displays an error message: ▪ PDF cannot be loaded, **Load PDF error (SR0100.3.6.1)** error message (GID-2669309). ▪ PDF cannot be displayed, **Display PDF error (SR0100.3.6.2)** error message (GID-2669310) ▪ PDF cannot be determined, **PDF ambiguous (SR0100.3.6.3)** error message link. When the error message has been confirmed, phase returns to the **Active mode (SR0100.1.2)** layout (GID-2671074) Otherwise continue with step 40.
Operator interaction	30	In case the automated upload results in an error, the operator can still trigger the upload of a PDF file manually with the **Load** button, see **Load PDF (SR0100.2.5)** function (GID-2671086). The same checks apply as for step 20. The phase needs to be completed manually by the operator.
Phase displays PDF file	40	Phase displays the PDF file in the PDF placeholder of the phase.
	50	Phase is completed automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.2 Main Path

Business logic related to the main path:

5.2.2.1 GID-2671085 SELECT PDF (SR0100.2.2)

- Function: PDF selection and loading

- Type: Main path

- Trigger: Operator opens file selection dialog

- Postcondition: Phase is active

Step	#	Description
Operator opens file selection dialog	10	Phase displays the file selection dialog. Starting directory is taken from the **File location (SR0100.8.3)** process parameter (GID-2671094).
	20	The displayed PDF files are filtered using the configured wildcards (* = multiple characters or ? = single character) for the file name. The file name is taken from the **File location (SR0100.8.3)** process parameter (GID-2671094).
Operator selects a PDF file	30	Phase closes the file selection dialog.
Phase displays PDF file	40	Phase displays the PDF file in the PDF placeholder of the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.2.2 GID-2671086 LOAD PDF (SR0100.2.5)

- Function: PDF loading

- Type: Main path

- Trigger: Operator loads a PDF file

- Postcondition: Phase is active

Step	#	Description
Operator loads a PDF file	10	Phase loads the PDF file according to the settings of the **File location (SR0100.8.3)** process parameter (GID-2671094). If one of the following issues occurs, phase displays an error message: ▪ PDF cannot be loaded, **Load PDF error (SR0100.3.6.1)** error message (GID-2669309). ▪ PDF cannot be displayed, **Display PDF error (SR0100.3.6.2)** error message (GID-2669310). ▪ PDF cannot be determined, **PDF ambiguous (SR0100.3.6.3)** error message (GID-2669311). When the error message has been confirmed, phase returns to the **Active mode (SR0100.1.2)** layout (GID-2671074). Otherwise continue with step 20.
Phase displays PDF file	20	Phase displays the PDF file in the PDF placeholder of the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.2.2.3 GID-2671087 CONFIRM PHASE (SR0100.2.3)

- ▪ Function: Completion of phase

- ▪ Type: Main path

- ▪ Trigger: Operator confirms phase

- ▪ Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	Operator confirms uploaded PDF file.
Phase checks setting of **Mandatory upload check (SR0100.8.6)** process parameter (GID-2671095)	20	If **Mandatory upload check** is enabled: ▪ If no PDF file has been uploaded, phase creates the **Mandatory upload check (SR0100.3.2.1)** system-triggered exception (GID-2671098). When the exception has been registered, phase returns to the **Active mode (SR0100.1.2)** layout (GID-2671074). ▪ If a PDF file has been uploaded or the system-triggered exception has been registered, continue with step 30.

Step	#	Description
	30	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3 Process Parameters (SR0100.8+)

The following process parameters define the behavior of the phase.

5.3.1 Instruction Table-specific Parameters

5.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

5.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

5.3.2 Instruction Link-specific Parameters

5.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671091). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

5.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

5.3.3 Basic Parameters

5.3.3.1 GID-2671092 INSTRUCTION (SR0100.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.3.2 GID-2671093 MODE (SR0100.8.2)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Selection** (default): Operator selects a PDF file. **Loading (pre-defined file)**: Operator triggers phase to load a pre-defined PDF file. **Automatic loading (pre-defined file)**: Phase automatically loads a pre-defined PDF file. **Automatic completion (pre-defined file)**: Phase automatically loads a pre-defined PDF file and is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.4 PDF File Parameters

5.3.4.1 GID-2671094 FILE LOCATION (SR0100.8.3)

Attribute	Type	Comment
Directory path	Text	Defines the directory path of the PDF file to be loaded. Environment variables are supported (e.g. %USERNAME%). If the **Mode (SR0100.8.2)** process parameter (GID-2671093)is set to **Selection**, the specified path is the starting point for the file selection dialog. The operator can navigate to another directory.
File name	Text	Defines the name of the PDF file to be loaded. If the **Mode (SR0100.8.2)** process parameter (GID-2671093)is set to **Selection**, wildcards are supported to restrict the number of displayed PDF files. Example: rep*.pdf displays all PDF files starting with rep. If the **Mode (SR0100.8.2)** process parameter (GID-2671093)is **not** set to **Selection**, the file name must be unique even if wildcards are used.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.5 Configuration of System-triggered Exceptions

5.3.5.1 GID-2671095 MANDATORY UPLOAD CHECK (SR0100.8.6)

Attribute	Type	Comment
Enabled	Flag	Controls if a check is performed. If not, the phase can be completed without a PDF file upload. If so, the phase can only be completed with a PDF file or if the **Mandatory upload check (SR0100.3.2.1)** system-triggered exception (GID-2671098)has been registered.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None, Low, Low (mandatory comment), Medium, Medium (mandatory comment), High, High (mandatory comment).** Default setting: **High.**
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters. **Mandatory** if the **Enabled** attribute is set to **Yes.**

See also **Mandatory upload check (SR0100.3.2.1)** system-triggered exception (GID-2671098).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.6 Configuration of User-triggered Exceptions

5.3.6.1 GID-2671096 SELECT MANUALLY (SR0100.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Select manually (SR0100.3.1.1)** user-triggered exception (GID-2671100).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.3.7 Configuration of Post-completion Exceptions

5.3.7.1 GID-2671097 REPLACE FILE (SR0100.8.5)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Replace file (SR0100.3.3.1)** post-completion exception [(GID-2671102)](#).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4 Exceptions (SR0100.3+)

The phase supports user-defined, user-triggered [(GID-2669307)](#), system-triggered [(GID-2669306)](#), and post-completion exceptions [(GID-2669308)](#) and their configuration by means of process parameters [(GID-2667950)](#).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

5.4.1 System-triggered Exceptions (SR0100.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

5.4.1.1 GID-2671098 MANDATORY UPLOAD CHECK (SR0100.3.2.1)

Representation of the exception:

- <Exception text>
(taken from **Mandatory upload check (SR0100.8.6)** process parameter (GID-2671095))

- Example:
Mandatory upload of the Sample Report is skipped.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4.1.2 GID-2671099 MANDATORY UPLOAD CHECK- LOGIC (SR0100.3.2.1.1)

- Trigger: Operator confirms phase

- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	Phase creates **Mandatory upload check (SR0100.3.2.1)** system-triggered exception.
Operator triggers exception	20	Phase records the exception.
Operator confirms exception	30	Phase returns to the **Active mode (SR0100.1.2)** layout (GID-2671074).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4.2 User-triggered Exceptions (SR0100.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

5.4.2.1 GID-2671100 Select manually (SR0100.3.1.1)

The **Select manually** exception allows an operator to select a PDF file manually. The settings of the **Mode (SR0100.8.2)** process parameter (GID-2671093)are ignored. If a PDF file has already been uploaded, the PDF file is replaced.

Representation during exception handling:

- Instruction:
  To display another document, select its PDF file.
  Select button.
  <Old PDF file>
  <Full path name of old PDF file>
  <Modification time of old PDF file>
  <New PDF>
  <Full path name of new PDF file>
  <Modification time of new PDF file>
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Select manually (SR0100.8.4)** process parameter (GID-2671096))
  Old PDF file: <Full path name>, <Modification time>
  New PDF file: <Full path name>, <Modification time>

  - Example:
    Manual selection
    Old PDF file: C:\upload\SOP001.PDF, 08/03/2012 10:43:26 AM CEST
    New PDF file: C:\upload\SOP002.PDF, 08/04/2012 10:43:26 AM CEST

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4.2.2 GID-2671101 Select manually - Logic (SR0100.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: PDF file is uploaded

Step	#	Description
Operator confirms exception	10	See **Select PDF (SR0100.2.2)** function (GID-2671085).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4.3 Post-completion Exceptions (SR0100.3.3+)

A post-completion exception is accessible via the Navigator and represented in the list of available post-completion exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following post-completion exceptions are available.

5.4.3.1 GID-2671102 REPLACE FILE (SR0100.3.3.1)

The **Replace file** exception allows an operator to manually replace the uploaded PDF file from the Navigator after the phase has been confirmed. If a PDF file has already been uploaded, the PDF file is replaced.

> **TIP**
>
> A recorded value could be used within branching. The correction of a value **does not influence** already processed branching decisions.

Representation of the exception:

- Instruction:
  To display another document, select its PDF file.
  Select button.
  <Old PDF file>
  <Full path name of old PDF file>
  <Modification time of old PDF file>
  <New PDF>
  <Full path name of new PDF file>
  <Modification time of new PDF file>
  Confirm button.

- <Exception text>
  (taken from **Replace file (SR0100.8.6)** process parameter (GID-2671095))
  Old PDF file: <Full path name>, <Modification time>
  New PDF file: <Full path name>, <Modification time>

  - Example:
    PDF file replaced (after phase completion).
    Old PDF file: C:\upload\SOP001.PDF, 08/03/2012 10:43:26 AM CEST
    New PDF file: C:\upload\SOP002.PDF, 08/04/2012 10:43:26 AM CEST

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.4.3.2 GID-2671103 REPLACE FILE - LOGIC (SR0100.3.3.1.1)

- Trigger: Phase is completed

- Postcondition: Post-completion exception is recorded

Step	#	Description
Operator triggers action	10	Phase displays Exception Window.
Operator confirms exception	30	See **Select PDF (SR0100.2.2)** function (GID-2671085). The **Load** button is disabled.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.5 Information Messages

There are no information messages available.

5.6 Questions

There are no questions available.

5.7 Decisions

There are no decisions available.

5.8 Error Messages (SR0100.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

5.8.1 GID-2669309 Load PDF error (SR0100.3.6.1)

UI text	Comment
Cannot load the PDF file, since the pre-defined file name (invalid file name) does not exist.	Message pack: PhaseBasicUploadPDF<version> Message ID: ParamFileLocation_NoFileFound_ErrorMsg
Cannot load the PDF file, since the pre-defined directory (<invalid directory>) does not exist.	Message pack: PhaseBasicUploadPDF<version> Message ID: ParamFileLocation_DirDoesNotExist_ErrorMsg
Cannot load the PDF file, since there is no directory path defined.	Message pack: PhaseBasicUploadPDF<version> Message ID: ParamFileLocation_NoDirConfigured_ErrorMsg
Cannot load the PDF file, since there is no file name defined.	Message pack: PhaseBasicUploadPDF<version> Message ID: ParamFileLocation_NoFileConfigured_ErrorMsg
Cannot display the PDF file, since it is password-protected.	Message pack: PhaseBasicUploadPDF<version> Message ID: PdfPasswordProtected_ErrorMsg
Cannot upload the PDF file, since it is encrypted and does not allow printing.	Message pack: PhaseBasicUploadPDF<version> Message ID: EncryptedFile_PrintingNotAllowed_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.2 GID-2669310 Display PDF error (SR0100.3.6.2)

UI text	Comment
Cannot display the PDF file.	Message pack: PhaseBasicUploadPDF<version> Message ID: displayPDF_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.8.3 GID-2669311 PDF ambiguous (SR0100.3.6.3)

UI text	Comment
Cannot load the PDF file, since the pre-defined file location contains more than one matching file.	Message pack: PhaseBasicUploadPDF<version> Message ID: ParamFileLocation_FileAmbiguous_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9 Output Variables (SR0100.9+)

The following output variables are available to reference the phase's output.

5.9.1 Instance count (Framework capability)

▪ Data type: Long

▪ Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
The count variable of a phase that has not been executed provides 0 as output value.

5.9.2 Start time (Framework capability)

▪ Data type: Timestamp

▪ Usage: The output variable provides the start time of the phase.

5.9.3 Completion time (Framework capability)

▪ Data type: Timestamp

▪ Usage: The output variable provides the completion time of the phase.

5.9.4 Identifier (Framework capability)

▪ Data type: String

▪ Usage: The output variable provides the identifier of the phase.

5.9.5 GID-2669316 PDF full path (SR0100.9.1)

▪ Data type: String

▪ Usage: The output variable provides the full path and file name of the uploaded PDF file.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.9.6 GID-2669317 PDF timestamp (SR0100.9.2)

- Data type: Timestamp

- Usage: The output variable provides the modification time of the uploaded PDF file.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

5.10 Configuration Keys (SR0100.11+)

The following configuration keys are available to configure the phase's behavior.

5.10.1 GID-2669318 Maximum file size (SR0100.11.1)

- Phase/UploadPdf/uploadMaximumFileSize

- **Type**: Long

- **Value**: N/A

- **Description**: Defines the maximum allowed file size in bytes of the PDF file to be uploaded. Default: 5000000

- **Range**: <=5000000

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6 Show URL Phase (SR0120+)

The **Show URL** phase allows to display PDF documents accessible via a URL.

> **TIP**
>
> Due to the diversity of available user authentication and SSL security solutions, the **Show URL** phase does not support user authentication or SSL security by default. However, the phase can be extended by a system integrator in order to support required customer-specific solutions.

An example use case is:

- Display an SOP
  An SOP is stored on the intranet or the file system. This very SOP can be displayed to the operator during execution.

The URL and the instruction text are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669321).

Anomalies that occur during processing are covered by the phase exception handling (GID-2667962)(e.g. document could not be loaded).

The URL of the displayed document is shown on the detail information button in the Navigator (e.g. www.PharmaAtItsBest.sop1.pdf).
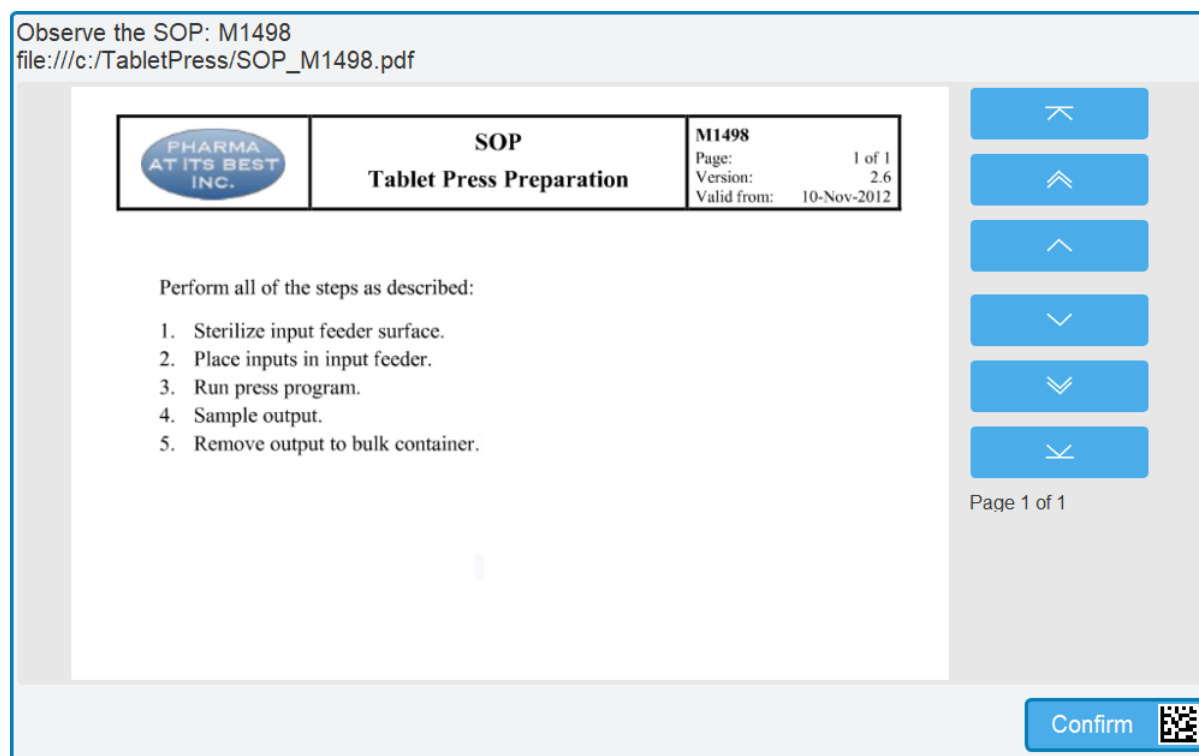

Figure 8: Show URL during execution

6.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669319), in the Navigator (GID-2669320), and in the sub-report (GID-2669321).

6.1.1 Representation during Execution (SR0120.1+)

The representation during execution depends on the phase mode.

6.1.1.1 GID-2671104 PREVIEW MODE (SR0120.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0120.8.1)** process parameter (GID-2671116))

2. <URL>
   (taken from **Document (SR0120.8.2)** process parameter (GID-2671117))

3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.2 GID-2671105 ACTIVE MODE (SR0120.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <URL>
   (taken from **Document (SR0120.8.2)** process parameter (GID-2671117))

3. <Instruction text>
   (taken from **Instruction (SR0120.8.1)** process parameter (GID-2671116))

4. <Document>, in a PDF viewer

5. Buttons to navigate through the document (**First page**, **Previous page**, **Previous line**, **Next line**, **Next page**, **Last page**)

6. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1.3 GID-2671106 COMPLETED MODE (SR0120.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0120.8.1)** process parameter (GID-2671116))

3. <URL>
   (taken from **Document (SR0120.8.2)** process parameter (GID-2671117))

4. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.2 Representation in Navigator (SR0120.4+)

The Navigator provides the following details:

6.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Mix inputs

6.1.2.2 GID-2671108 INFORMATION COLUMN (SR0120.4.1)

- <Phase name>

  - Example: Cleaning SOP V1.0

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.2.3 ACTION COLUMN (FRAMEWORK CAPABILITY)

- There are no phase-specific actions available.

6.1.3 Representation in Sub-report (SR0120.5+)

The sub-report contains the following information:

6.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- \<Start time>

- \<Completion time>

- \<Unit procedure> / \<operation> / \<phase>

- \<Work center> / \<station> / \<device> - \<phase completion user>

6.1.3.2 GID-2671111 SUB-REPORT ELEMENTS (SR0120.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- URL

- Instruction text

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2 Business Logic (SR0120.2+)

The phase implements the following business logic.

6.2.1 GID-2669322 Display document (SR0120.2.1)

- Function: Display a document

- Trigger: Phase becomes active

- Postcondition: Document was displayed

Step	#	Description
Phase activation	10	Phase displays document.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3 Process Parameters (SR0120.8+)

The following process parameters define the behavior of the phase.

6.3.1 Instruction Table-specific Parameters

6.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

6.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

6.3.2 Instruction Link-specific Parameters

6.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671115). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

6.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

6.3.3 Basic Parameters

6.3.3.1 GID-2671116 INSTRUCTION (SR0120.8.1)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).
Column 2	HTML text	Not used.
Column 3	HTML text	

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.3.2 GID-2671117 DOCUMENT (SR0120.8.2)

Attribute	Type	Comment
URL	Text	URL of the document to be displayed. The document will be shown within a PDF viewer.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.3.4 Configuration of System-triggered Exceptions

6.3.4.1 GID-2671118 LOADING FAILED (SR0120.8.3)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Loading failed (SR0120.3.2.1)** system-triggered exception (GID-2671119).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.4 Exceptions (SR0120.3+)

The phase supports user-defined, user-triggered (GID-2669328), system-triggered (GID-2669327), and post-completion exceptions (GID-2669329)and their configuration by means of process parameters (GID-2667961).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

6.4.1 System-triggered Exceptions (SR0120.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

6.4.1.1 GID-2671119 LOADING FAILED (SR0120.3.2.1)

Representation of the exception:

In case the file cannot be loaded e.g. because the URL is not valid or the file is password-protected, the system triggers this exception.

- \<Exception text\>
  (taken from **Loading failed (SR0120.8.3)** process parameter (GID-2671118))
  Cannot load \<URL\>

    - Example:
      SOP 0001 could not be loaded.
      Cannot load www.PharmaAtItsBest.sop0001.pdf

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.4.1.2 GID-2671120 LOADING FAILED - LOGIC (SR0120.3.2.1.1)

- Trigger: Loading of document failed

- Postcondition: Exception is recorded

Step	#	Description
Operator triggers exception	10	Phase records the exception.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.4.2 User-triggered Exceptions

There are no user-triggered exceptions available.

6.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

6.5 Information Messages

There are no information messages available.

6.6 Questions

There are no questions available.

6.7 Decisions

There are no decisions available.

6.8 Error Messages

There are no error messages available.

6.9 Output Variables

The following output variables are available to reference the phase's output.

6.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

6.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

6.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

6.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

7 Create Workflow Phase (SR0130+)

The **Create workflow** phase allows to create a workflow during the execution of an order or workflow.
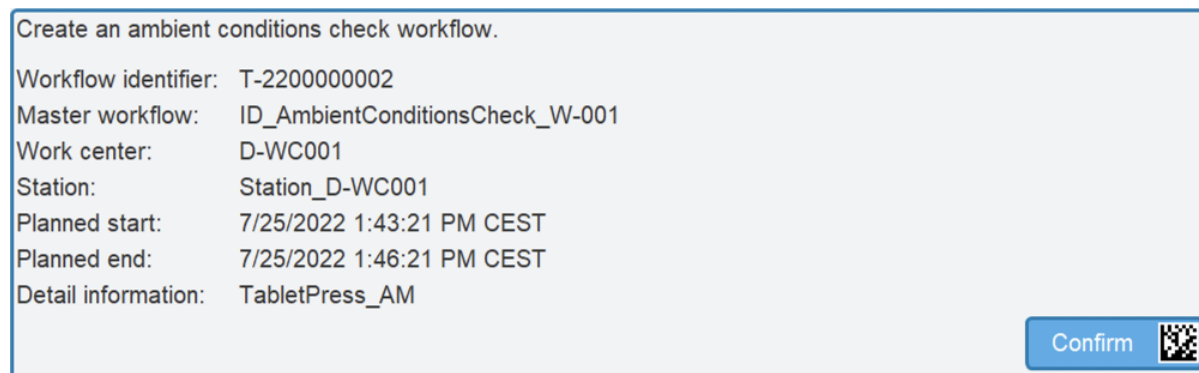
Example use cases are:

- During order execution the container to be used is contaminated and needs to be cleaned. An ad-hoc workflow to clean the container is created and appended to the order.

- The flow rate of a filter is too low and the filter needs to be rinsed. An ad-hoc workflow is created to rinse the filter.

The instruction text, the used master workflow identifier and the workflow identifier of the created workflow, the optional configured work center, station, planned start, planned end, and detail information are stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669336).

After completion the phase displays the defined data.

The navigator displays the identifier of the created workflow.


```
Create an ambient conditions check workflow.

Workflow identifier:   T-2200000002
Master workflow:       ID_AmbientConditionsCheck_W-001
Work center:           D-WC001
Station:               Station_D-WC001
Planned start:         7/25/2022 1:43:21 PM CEST
Planned end:           7/25/2022 1:46:21 PM CEST
Detail information:    TabletPress_AM

                                          Confirm
```

Figure 9: Create workflow during execution

7.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669334), in the Navigator (GID-2669335), and in the sub-report (GID-2669336).

7.1.1 Representation during Execution (SR0130.1+)

The representation during execution depends on the phase mode.

7.1.1.1 GID-2671121 PREVIEW MODE (SR0130.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0130.8.1)** process parameter (GID-2671138))

2. Workflow identifier (taken from **Workflow definition (SR0130.8.3)** process parameter (GID-2671140))
    Master workflow (taken from **Master workflow (SR0130.8.4)** process parameter (GID-2671141))
    Work center (taken from **Work center (SR0130.8.6)** process parameter (GID-2671143))
    Station (taken from **Station (SR0130.8.7)** process parameter (GID-2671144))
    Planned start (taken from **Planned start (SR0130.8.9)** process parameter (GID-2671146))
    Planned end (taken from **Planned end (SR0130.8.10)** process parameter (GID-2671147))
    Detail information (taken from **Detail information (SR0130.8.11)** process parameter (GID-2671148)
    The system displays only the labels and their data for which input has been configured and is already evaluated.

3. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.1.2 GID-2671122 ACTIVE MODE (SR0130.1.2)

1. Instruction table panel and/or instruction link panel
    (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
    (taken from **Instruction (SR0130.8.1)** process parameter (GID-2671138))

3. Workflow identifier (taken from **Workflow definition (SR0130.8.3)** process parameter (GID-2671140))
    Master workflow (taken from **Master workflow (SR0130.8.4)** process parameter (GID-2671141))
    Work center (taken from **Work center (SR0130.8.6)** process parameter (GID-2671143))
    Station (taken from **Station (SR0130.8.7)** process parameter (GID-2671144))
    Planned start (taken from **Planned start (SR0130.8.9)** process parameter (GID-2671146))
    Planned end (taken from **Planned end (SR0130.8.10)** process parameter (GID-2671147))
    Detail information (taken from **Detail information (SR0130.8.11)** process parameter (GID-2671148))
    The system displays only the labels and their data for which input has been configured and is already evaluated.

4. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.1.3 GID-2671123 COMPLETED MODE (SR0130.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0130.8.1)** process parameter (GID-2671138))

3. Workflow identifier (taken from **Workflow definition (SR0130.8.3)** process parameter (GID-2671140)) or the generated workflow identifier if the parameter is not specified)
   Master workflow (taken from **Master workflow (SR0130.8.4)** process parameter (GID-2671141))
   Work center (taken from **Work center (SR0130.8.6)** process parameter (GID-2671143))
   Station (taken from **Station (SR0130.8.7)** process parameter (GID-2671144))
   Planned start (taken from **Planned start (SR0130.8.9)** process parameter (GID-2671146)
   Planned end (taken from **Planned end (SR0130.8.10)** process parameter (GID-2671147))
   Detail information (taken from **Detail information (SR0130.8.11)** process parameter (GID-2671148))
   The system displays only the labels and their data for which input has been configured or a default was generated.

4. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.2 Representation in Navigator (SR0130.4+)

The Navigator provides the following details:

7.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Create cleaning workflow

7.1.2.2 GID-2671125 INFORMATION COLUMN (SR0130.4.1)

- <Workflow identifier>

  - Example: WF1900002485

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

7.1.3 Representation in Sub-report (SR0130.5+)

The sub-report contains the following information:

7.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

7.1.3.2 GID-2671128 SUB-REPORT ELEMENTS (SR0130.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- The system only prints the labels and their data for which input has been configured or a default was generated:

  - Workflow identifier (taken from **Workflow definition (SR0130.8.3)** process parameter (GID-2671140)) or the generated default value

  - Master workflow (taken from **Master workflow (SR0130.8.4)** process parameter (GID-2671141))

  - Work center (taken from **Work center (SR0130.8.6)** process parameter (GID-2671143))

  - Station (taken from **Station (SR0130.8.7)** process parameter (GID-2671144)

  - Planned start (taken from **Planned start (SR0130.8.9)** process parameter (GID-2671146))

  - Planned end (taken from **Planned end (SR0130.8.10)** process parameter (GID-2671147))

  - Detail information (taken from **Detail information (SR0130.8.11)** process parameter (GID-2671148))

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2 Business Logic (SR0130.2+)

The phase implements the following business logic.

7.2.1 *Phase Mode*

Business logic related to phase modes.

7.2.1.1 GID-2671129 MANUAL COMPLETION MODE (SR0130.2.1)

- Function: **Manual completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0130.1.2)** layout (GID-2671122).
Phase completion	30	See **Confirm phase (SR0130.2.3)** function (GID-2671131).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.1.2 GID-2671130 AUTOMATIC COMPLETION MODE (SR0130.2.2)

- Function: **Automatic completion** mode of phase
- Type: Phase mode
- Trigger: Phase becomes active
- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0130.1.2)** layout (GID-2671122)..
	20	The system tries to confirm the phase immediately as if the operator had used the **Confirm** button of the phase to trigger the **Confirm phase (SR0130.2.3)** function (GID-2671131).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.2 Main Path

Business logic related to the main path:

7.2.2.1 GID-2671131 CONFIRM PHASE (SR0130.2.3)

- Function: Completion of phase

- Trigger: Operator confirms phase

- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	Operator confirms that the workflow can be created.
System checks if work center and station exist	20	If the work center configured with the **Work center (SR0130.8.6)** process parameter (GID-2671143) does not exist, phase displays the **Work center does not exist (SR0130.3.6.3)** error message (GID-2669348). If the station configured with the **Station (SR0130.8.7)** process parameter (GID-2671144) does not exist, phase displays the **Station does not exist (SR0130.3.6.4)** error message (GID-2669349). If both the configured work center and the configured station do not exist, a combined error message is displayed. When the error message has been confirmed, phase returns to the **Active mode (SR0130.1.2)** layout (GID-2671122). Otherwise continue with step 30.
System checks consistency between work center and station	30	If the value of the **Work center (SR0130.8.6)** process parameter (GID-2671143)is not the work center of the station configured with the **Station (SR0130.8.7)** process parameter (GID-2671144), phase displays the **Station and work center inconsistency (SR0130.3.6.1)** error message (GID-2669346). When the error message has been confirmed, phase returns to the **Active mode (SR0130.1.2)** layout (GID-2671122). Otherwise continue with step 35.
System checks master workflow	35	If no approved master workflow recipe exists for the identifier configured with the **Master workflow (SR0130.8.6)** process parameter (GID-2671143), phase displays the **Master workflow not approved (SR0130.3.6.2)** error message (GID-2669347). When the error message has been confirmed, phase returns to the **Active mode (SR0130.1.2)** layout (GID-2671122). Otherwise continue with step 40.

Step	#	Description
System creates workflow	40	If a workflow with the identifier configured with the **Workflow definition (SR0130.8.6)** process parameter (GID-2671143)already exists, phase displays the **Duplicate workflow identifier (SR0130.3.6.5)** error message (GID-2669350). When the error message has been confirmed, phase returns to the **Active mode (SR0130.1.2)** layout (GID-2671122). Otherwise the workflow with the configured data for ▪ planned start according to the **Planned start (SR0130.8.9)** process parameter (GID-2671146) ▪ planned end according to the **Planned end (SR0130.8.10)** process parameter (GID-2671147) ▪ detail information according to the **Detail information (SR0130.8.11)** process parameter (GID-2671148) ▪ work center and station according to the Work center and station determination (SR0130.2.4) function (GID-2671132) is created and released. If the phase is running in the context of an order unit procedure, a treatment ID is defined for the order, and the system is configured accordingly (see **Enable and Configure Treatment ID Support (SR0130.11.1)** configuration key) (GID-2669360), the workflow inherits the treatment ID from the order.
System appends workflow	45	If the **Append Workflow (SR0130.8.5)** process parameter (GID-2671142) is set to **Yes** and the phase is running in the context of an order unit procedure, the created workflow is appended to the unit procedure. At start of the workflow the system will not ask the user if the workflow shall be appended to an order.
System starts workflow	50	If the **Start workflow automatically (SR0130.8.8)** process parameter (GID-2671145)is set to **Yes** and ▪ a station is set with the **Station (SR0130.8.7)** process parameter (GID-2671144), then the workflow is started at this station, ▪ the workflow is dispatched to one work center, then the workflow is started at this work center, ▪ the workflow is dispatched to several work centers, then the workflow is only started at the current work center and only if it is one of the work centers to which the workflow has been dispatched, otherwise the workflow is not started, ▪ the workflow is dispatched neither to a station nor to a work center, then the workflow is started at the current work center. Starting a workflow means it will be available in the Cockpit with its unit procedure and startable operation(s).
	60	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.2.2 GID-2671132 WORK CENTER AND STATION DETERMINATION (SR0130.2.4)

- Function: Determine the work center and station for the workflow

- Trigger: Phase creates the workflow

- Postcondition: Workflow is dispatched to work center and station

Step	#	Description
Station defined	10	If the **Station (SR0130.8.7)** process parameter (GID-2671144)has a value, the workflow unit procedure will be dispatched to the station and the work center of the station. Station assignments defined with the master workflow are ignored. Otherwise continue with step 20.
Work center defined	20	If the **Work center (SR0130.8.6)** process parameter (GID-2671143)has a value, the unit procedure of the workflow will be dispatched to this work center. Station assignments defined with the master workflow are ignored. Otherwise continue with step 30.
Stations defined at recipe	30	If the master workflow has stations assigned to its unit procedure, the unit procedure of the workflow will be dispatched to the stations and work centers defined with the master workflow. Otherwise continue with step 40.
Work center defined at recipe	40	If the master workflow has only work centers assigned to its unit procedure, the unit procedure of the workflow will be dispatched to these work centers.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3 Process Parameters (SR0130.8+)

The following process parameters define the behavior of the phase.

7.3.1 Instruction Table-specific Parameters

7.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

7.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

7.3.2 Instruction Link-specific Parameters

7.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671136). Example: Refer to {SOP1270} for guidance.
		Maximum length is 2000 characters (including HTML tags).

7.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional.
		Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.
		Maximum length is 256 characters.

7.3.3 Configuration of User-triggered Exceptions

7.3.3.1 GID-2671137 SKIP WORKFLOW CREATION (SR0130.8.12)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Skip workflow creation (SR0130.3.1.1)** user-triggered exception (GID-2671149).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4 Basic Parameters

7.3.4.1 GID-2671138 INSTRUCTION (SR0130.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.2 GID-2671139 MODE (SR0130.8.2)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Manual completion** (default): Operator confirms the phase. **Automatic completion**: Phase automatically tries to confirm the phase.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.3 GID-2671140 WORKFLOW DEFINITION (SR0130.8.3)

Attribute	Type	Comment
Identifier	String	Optional parameter to define a unique workflow identifier for the workflow to be created. If empty, a workflow identifier with the configured default prefix is generated. Maximum length is 12 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.4 GID-2671141 MASTER WORKFLOW (SR0130.8.4)

Attribute	Type	Comment
Identifier	String	Defines the master workflow identifier without version to be used for generating the workflow. The Master Workflow Selection editor (**Framework capability**) only lists **Scheduled** and **Approved** master workflows. Maximum length is 50 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.5 GID-2671142 APPEND WORKFLOW (SR0130.8.5)

Attribute	Type	Comment
Enabled	Flag	Controls if the created workflow is automatically appended to the current unit procedure. If the phase runs in the context of a workflow, the parameter is ignored. Default setting: **Yes**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.6 GID-2671143 WORK CENTER (SR0130.8.6)

Attribute	Type	Comment
Identifier	String	Optional parameter to define the work center to which the created workflow is dispatched. The Work Center Selection editor is a **Framework capability.** Maximum length is 20 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.7 GID-2671144 STATION (SR0130.8.7)

Attribute	Type	Comment
Identifier	String	Optional parameter to define the station to which the created workflow is dispatched. The Station Selection editor is a **Framework capability.** Maximum length is 20 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.8 GID-2671145 START WORKFLOW AUTOMATICALLY (SR0130.8.8)

Attribute	Type	Comment
Enabled	Flag	Controls if the created workflow will be available in the cockpit if it is dispatched to a work center or a station. Default setting: **No**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.9 GID-2671146 PLANNED START (SR0130.8.9)

Attribute	Type	Comment
Timestamp	Timestamp	Optional information shown to an operator in the workflow processing list of the work center to which a workflow hat been dispatched, unless the workflow is started automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.10 GID-2671147 PLANNED END (SR0130.8.10)

Attribute	Type	Comment
Timestamp	Timestamp	Optional information shown to an operator in the workflow processing list of the work center to which a workflow hat been dispatched, unless the workflow is started automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4.11 GID-2671148 Detail information (SR0130.8.11)

Attribute	Type	Comment
Value	String	Optional information shown to an operator in the workflow processing list of the work center to which a workflow hat been dispatched, unless the workflow is started automatically. Maximum length is 20 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.4 Exceptions (SR0130.3+)

The phase supports user-defined, user-triggered (GID-2669344), system-triggered (GID-2669343), and post-completion exceptions (GID-2669345) and their configuration by means of process parameters (GID-2667939).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

7.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

7.4.2 User-triggered Exceptions (SR0130.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

7.4.2.1 GID-2671149 Skip workflow creation (SR0130.3.1.1)

The **Skip workflow creation** exception allows an operator to skip the phase if the situation on the shop floor does not require the creation of a workflow anymore. To solve issues caused by phase misconfiguration or error cases, the framework provides the **Abort Phase (SR1200.3.1)** and the **Repair Phase (SR1200.3.2)** functions, see "Functional Requirement Specification Execution Framework" [A1] (GID-2667978).

Representation during exception handling:

- Instruction
  Skip the workflow creation.
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Skip workflow parameter (SR0130.8.12)** process parameter (GID-2671137))
  Skip the workflow creation.

  - Example:
    Supervisor needs to be informed to create the required workflow!
    Skip the workflow creation.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.2.2 GID-2671150 SKIP WORKFLOW CREATION - LOGIC (SR0130.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: **Create workflow** phase is skipped.

Step	#	Description
Operator confirms exception	10	Phase shows exception description to be signed according to **Skip workflow creation (SR0130.8.12)** process parameter (GID-2671137).
Operator signs exception	20	- Phase records the exception. - Operator completes the phase manually without creation of a workflow.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

7.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

7.5 Information Messages

There are no information messages available.

7.6 Questions

There are no questions available.

7.7 Decisions

There are no decisions available.

7.8 Error Messages (SR0130.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

7.8.1 GID-2669346 Station and work center inconsistency (SR0130.3.6.1)

UI text	Comment
<Information that the configured work center is not the work center of the configured station.>	Message pack: PhaseEbrCreateWorkflow<version> Message ID: WorkcenterStationInconsistent_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.2 GID-2669347 Master workflow not approved (SR0130.3.6.2)

UI text	Comment
<Information that there is no approved master workflow with the configured identifier available.>	Message pack: PhaseEbrCreateWorkflow<version> Message ID: NoValidWorkflow_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.3 GID-2669348 Work center does not exist (SR0130.3.6.3)

UI text	Comment
<Information that the configured work center does not exist.>	Message pack: PhaseEbrCreateWorkflow<version> Message ID: NoValidWorkcenter_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.4 GID-2669349 Station does not exist (SR0130.3.6.4)

UI text	Comment
<Information that the configured station does not exist.>	Message pack: PhaseEbrCreateWorkflow<version> Message ID: NoValidStation_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.8.5 GID-2669350 Duplicate workflow identifier (SR0130.3.6.5)

UI text	Comment
<Information that the configured workflow identifier is already in use.>	Message pack: PhaseEbrCreateWorkflow<version> Message ID: BadWorkflowIdentifier_Error

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.9 Output Variables (SR0130.9+)

The following output variables are available to reference the phase's output.

7.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

7.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

7.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

7.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

7.9.5 GID-2669355 Workflow identifier (SR0130.9.1)

- Data type: String

- Usage: The output variable provides the identifier of the created workflow taken from the **Workflow definition (SR0130.8.3)** process parameter (GID-2671140)or the generated default value.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.9.6 GID-2669356 Planned start (SR0130.9.2)

- Data type: Timestamp

- Usage: The output variable provides the planned start time of the workflow taken from **Planned start (SR0130.8.9)** process parameter (GID-2671146).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.9.7 GID-2669357 Planned end (SR0130.9.3)

- Data type: Timestamp

- Usage: The output variable provides the planned end time of the workflow taken from **Planned end (SR0130.8.10)** process parameter (GID-2671147).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.9.8 GID-2669358 Detail information (SR0130.9.4)

- Data type: String

- Usage: The output variable provides the detail information about the workflow taken from **Detail information (SR0130.8.11)** process parameter (GID-2671148).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.9.9 GID-2669359 Creation result (SR0130.9.5)

- Data type: String

- Values: CREATED, SKIPPED

- Usage: The output variable states if a workflow was created or the phase was skipped.

- The value is CREATED if the creation of the workflow was successful.

- The value is SKIPPED if no workflow was created and the phase was skipped by the **Skip workflow creation (SR0130.3.1.1)** user triggered exception (GID-2671149).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.10 Configuration Keys (SR0130.11+)

The following configuration keys are available to configure the phase's behavior.

7.10.1 GID-2669360 Enable and Configure Treatment ID Support (SR0130.11.1)

- Phase/TreatmentIDSupport

- **Type**: String

- **Value**: Off

- **Description**: The configuration applies to material identification with the **D Identify material** phase and the **Identify material** phase and to workflow creation with the **Create workflow** phase.
  If the value is set to **Off**, no treatment ID is checked during material identification and a created workflow does not inherit the treatment ID of the order.
  If the value is set to **TreatmentIDMandatory**, all orders need to have a treatment ID set. If the identified batch has a treatment ID, it must be equal to the order's treatment ID.
  If the value is set to **TreatmentIDOptional**, an order does not have to have a treatment ID set. If the identified batch has a treatment ID, it has to be equal to the order's treatment ID.

- **Evaluated**: At sublot or batch identification and at workflow creation.

- **Range**: [Off, TreatmentIDMandatory, TreatmentIDOptional]

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8 Write Context Data Phase (SR0140+)

The **Write context data** phase allows to store processing data from an order or workflow for later use.

Example use cases are:

- Store the equipment identifier of a filter to allow a filter test workflow to check that it runs the test against the planned filter.

- Store and increase a counter value in a loop for a number of used containers until a planned number of containers per type has been filled.

Each recorded value is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669363).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668203)(e.g. context and key check).

After completion, the phase displays the data written to the context.

The Navigator displays the identifier of the context.

Figure 10: Write context data during execution

8.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669361), in the Navigator (GID-2669362), and in the sub-report (GID-2669363).

8.1.1 Representation during Execution (SR0140.1+)

The representation during execution depends on the phase mode.

8.1.1.1 GID-2671151 PREVIEW MODE (SR0140.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0140.8.1)** process parameter (GID-2671166))

2. Context identifier (taken from **Context definition (SR0140.8.3)** process parameter (GID-2671168).

3. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:

- **BigDecimal Value Bundle**:

  - Key
    (taken from the [BigDecimal] **Master bundle identifier (SR0140.8.6)** process parameter [(GID-2671172)](#))

  - Value
    (taken from the [BigDecimal] **Master bundle identifier (SR0140.8.6)** process parameter [(GID-2671172)](#))

- **Boolean Value Bundle**:

  - Key
    (taken from the [Boolean] **Master bundle identifier (SR0140.8.7)** process parameter [(GID-2671174)](#))

  - Value
    (taken from the [Boolean] **Master bundle identifier (SR0140.8.7)** process parameter [(GID-2671174)](#))

- **Duration Value Bundle**:

  - Key
    (taken from the [Duration] **Master bundle identifier (SR0140.8.8)** process parameter [(GID-2671176)](#)

  - Value
    (taken from the [Duration] **Master bundle identifier (SR0140.8.8)** process parameter [(GID-2671176)](#))

- **Long Value Bundle**:

  - Key
    (taken from the [Long] **Master bundle identifier (SR0140.8.9)** process parameter [(GID-2671178)](#))

  - Value
    (taken from the [Long] **Master bundle identifier (SR0140.8.9)** process parameter [(GID-2671178)](#))

- **Measured Value Bundle**:

  - Key
    (taken from the [Measured Value] **Master bundle identifier (SR0140.8.10)** process parameter [(GID-2671180)](#))

  - Value
    (taken from the [Measured Value] **Master bundle identifier (SR0140.8.10)** process parameter [(GID-2671180)](#))

- **String Value Bundle**:

    - Key
      (taken from the [String] **Master bundle identifier (SR0140.8.11)** process parameter [(GID-2671182)](#))

    - Value
      (taken from the [String] **Master bundle identifier (SR0140.8.11)** process parameter [(GID-2671182)](#))

- **Timestamp Value Bundle**:

    - Key
      (taken from the [Timestamp] **Master bundle identifier (SR0140.8.12)** process parameter [(GID-2671184)](#))

    - Value
      (taken from the [Timestamp] **Master bundle identifier (SR0140.8.12)** process parameter [(GID-2671184)](#))

4. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

8.1.1.2 GID-2671152 ACTIVE MODE (SR0140.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
   (taken from **Instruction (SR0140.8.1)** process parameter [(GID-2671166)](#))

3. Context identifier (taken from **Context definition (SR0140.8.3)** process parameter [(GID-2671168)](#))

4. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:

- **BigDecimal Value Bundle**:

    - Key
      (taken from the [BigDecimal] **Master bundle identifier (SR0140.8.6)** process parameter [(GID-2671172)](#))

    - Value
      (taken from the [BigDecimal] **Master bundle identifier (SR0140.8.6)** process parameter [(GID-2671172)](#))

- **Boolean Value Bundle**:

    - Key
    (taken from the [Boolean] **Master bundle identifier (SR0140.8.7)** process parameter (GID-2671174))

    - Value
    (taken from the [Boolean] **Master bundle identifier (SR0140.8.7)** process parameter (GID-2671174))

- **Duration Value Bundle**:

    - Key
    (taken from the [Duration] **Master bundle identifier (SR0140.8.8)** process parameter (GID-2671176)

    - Value
    (taken from the [Duration] **Master bundle identifier (SR0140.8.8)** process parameter (GID-2671176))

- **Long Value Bundle**:

    - Key
    (taken from the [Long] **Master bundle identifier (SR0140.8.9)** process parameter (GID-2671178))

    - Value
    (taken from the [Long] **Master bundle identifier (SR0140.8.9)** process parameter (GID-2671178))

- **Measured Value Bundle**:

    - Key
    (taken from the [Measured Value] **Master bundle identifier (SR0140.8.10)** process parameter (GID-2671180))

    - Value
    (taken from the [Measured Value] **Master bundle identifier (SR0140.8.10)** process parameter (GID-2671180))

- **String Value Bundle**:

    - Key
    (taken from the [String] **Master bundle identifier (SR0140.8.11)** process parameter (GID-2671182))

    - Value
    (taken from the [String] **Master bundle identifier (SR0140.8.11)** process parameter (GID-2671182))

- **Timestamp Value Bundle**:

    - Key
    (taken from the [Timestamp] **Master bundle identifier (SR0140.8.12)** process parameter [(GID-2671184)](GID-2671184))

    - Value
    (taken from the [Timestamp] **Master bundle identifier (SR0140.8.12)** process parameter [(GID-2671184)](GID-2671184))

5. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.1.1.3 GID-2671153 COMPLETED MODE (SR0140.1.3)

1. Instruction table panel and/or instruction link panel
(only if an instruction table and/or instruction link is defined for the phase)

2. <Instruction text>
(taken from **Instruction (SR0140.8.1)** process parameter [(GID-2671166)](GID-2671166))

3. Context identifier (taken from **Context definition (SR0140.8.3)** process parameter [(GID-2671168)](GID-2671168).

4. List of up to 50 bundle parameters in the order of the bundle-specific process parameters:

    - **BigDecimal Value Bundle**:

        - Key
        (taken from the [BigDecimal] **Master bundle identifier (SR0140.8.6)** process parameter [(GID-2671172)](GID-2671172))

        - Value
        (taken from the [BigDecimal] **Master bundle identifier (SR0140.8.6)** process parameter [(GID-2671172)](GID-2671172))

    - **Boolean Value Bundle**:

        - Key
        (taken from the [Boolean] **Master bundle identifier (SR0140.8.7)** process parameter [(GID-2671174)](GID-2671174))

        - Value
        (taken from the [Boolean] **Master bundle identifier (SR0140.8.7)** process parameter [(GID-2671174)](GID-2671174))

- **Duration Value Bundle**:

  - Key
    (taken from the [Duration] **Master bundle identifier (SR0140.8.8)** process parameter (GID-2671176))

  - Value
    (taken from the [Duration] **Master bundle identifier (SR0140.8.8)** process parameter (GID-2671176))

- **Long Value Bundle**:

  - Key
    (taken from the [Long] **Master bundle identifier (SR0140.8.9)** process parameter (GID-2671178))

  - Value
    (taken from the [Long] **Master bundle identifier (SR0140.8.9)** process parameter (GID-2671178))

- **Measured Value Bundle**:

  - Key
    (taken from the [Measured Value] **Master bundle identifier (SR0140.8.10)** process parameter (GID-2671180))

  - Value
    (taken from the [Measured Value] **Master bundle identifier (SR0140.8.10)** process parameter (GID-2671180))

- **String Value Bundle**:

  - Key
    (taken from the [String] **Master bundle identifier (SR0140.8.11)** process parameter (GID-2671182))

  - Value
    (taken from the [String] **Master bundle identifier (SR0140.8.11)** process parameter (GID-2671182))

- **Timestamp Value Bundle**:

  - Key
    (taken from the [Timestamp] **Master bundle identifier (SR0140.8.12)** process parameter (GID-2671184))

  - Value
    (taken from the [Timestamp] **Master bundle identifier (SR0140.8.12)** process parameter (GID-2671184))

5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.1.2 Representation in Navigator (SR0140.4+)

The Navigator provides the following details:

8.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Write workflow context

8.1.2.2 GID-2671155 INFORMATION COLUMN (SR0140.4.1)

- <Context identifier> (taken from **Context definition (SR0140.8.3)** process parameter (GID-2671168).

  - Example: WF1900002485

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

8.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

8.1.3 Representation in Sub-report (SR0140.5+)

The sub-report contains the following information:

8.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

8.1.3.2 GID-2671158 SUB-REPORT ELEMENTS (SR0140.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Context identifier

- Table of values that have been written (in the order of the bundle-specific process parameters):

- BigDecimal Value Bundles:
    - Key
    - Value
- Boolean Value Bundles
    - Key
    - Value
- Duration Value Bundles:
    - Key
    - Value
- Long Value Bundles:
    - Key
    - Value
- Measured Value Bundles:
    - Key
    - Value
- String Value Bundles:
    - Key
    - Value
- Timestamp Value Bundles:
    - Key
    - Value

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.2 Business Logic (SR0140.2+)

The phase implements the following business logic.

8.2.1 Phase Mode

Business logic related to phase modes.

8.2.1.1 GID-2671159 MANUAL COMPLETION MODE (SR0140.2.1)

- Function: **Manual completion** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0140.1.2)** layout (GID-2671152).
Phase completion	20	See **Confirm phase (SR0140.2.3)** function (GID-2671161).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.2.1.2 GID-2671160 AUTOMATIC COMPLETION MODE (SR0140.2.2)

- Function: **Automatic completion** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0140.1.2)** layout (GID-2671152).
	20	The system tries to confirm the phase immediately as if the operator had used the **Confirm** button of the phase to trigger the **Confirm phase (SR0140.2.3)** function (GID-2671161).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

8.2.2 Main Path

Business logic related to the main path:

8.2.2.1 GID-2671161 CONFIRM PHASE (SR0140.2.3)

- Function: Completion of phase

- Trigger: Operator confirms phase

- Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	Operator confirms that the context data shall be stored.
System checks context identifier	20	If no context identifier is configured with the **Context definition (SR0140.8.3)** process parameter (GID-2671168), phase displays the **Context identifier not defined (SR0140.3.6.2)** error message (GID-2669382). When the error message has been confirmed, phase returns to the Active mode (SR0140.1.2) layout. Otherwise continue with step 30.
System checks keys	30	If no key is configured at any of the bundle process parameters - [BigDecimal] Master (Bundle identifier) (SR0140.8.6) process parameter (GID-2671172), - [Boolean] Master (Bundle identifier) (SR0140.8.7) process parameter (GID-2671174), - [Duration] Master (Bundle identifier) (SR0140.8.8) process parameter (GID-2671176), - [Long] Master (Bundle identifier) (SR0140.8.9) process parameter (GID-2671178), - [MeasuredValue] Master (Bundle identifier) (SR0140.8.10) process parameter (GID-2671180), - [String] Master (Bundle identifier) (SR0140.8.11) process parameter (GID-2671182), - [Timestamp] Master (Bundle identifier) (SR0140.8.12) process parameter (GID-2671184), phase displays the **Key not defined (SR0140.3.6.1)** error message (GID-2669381). When the error message has been confirmed, phase returns to the **Active mode (SR0140.1.2)** layout (GID-2671152). Otherwise continue with step 40.

Step	#	Description
System checks data type consistency	40	If context data for the context identifier defined by **Context definition (SR0140.8.3)** process parameter (GID-2671168)and key defined at any of the bundle process parameters • [BigDecimal] Master (Bundle identifier) (SR0140.8.6) process parameter (GID-2671172), • [Boolean] Master (Bundle identifier) (SR0140.8.7) process parameter (GID-2671174) • [Duration] Master (Bundle identifier) (SR0140.8.8) process parameter (GID-2671176), • [Long] Master (Bundle identifier) (SR0140.8.9) process parameter (GID-2671178) • [MeasuredValue] Master (Bundle identifier) (SR0140.8.10) process parameter (GID-2671180), • [String] Master (Bundle identifier) (SR0140.8.11) process parameter (GID-2671182), • [Timestamp] Master (Bundle identifier) (SR0140.8.12) process parameter (GID-2671184), already exists with a different data type than that of the bundle process parameters, phase displays the **Change of data type not allowed (SR0140.3.6.3)** error message (GID-2669383)When the error message has been confirmed, phase returns to the **Active mode (SR0140.1.2)** layout (GID-2671152). Otherwise continue with step 50.
System checks if context data already exists	50	If check is enabled according to the **Context and key check (SR0140.8.5)** process parameter (GID-2671169)and both context data for the context identifier defined by the **Context definition (SR0140.8.3)** process parameter (GID-2671168)and key defined at any of the bundle process parameters • [BigDecimal] Master (Bundle identifier) (SR0140.8.6) process parameter (GID-2671172), • [Boolean] Master (Bundle identifier) (SR0140.8.7) process parameter (GID-2671174), • [Duration] Master (Bundle identifier) (SR0140.8.8) process parameter (GID-2671176), • [Long] Master (Bundle identifier) (SR0140.8.9) process parameter (GID-2671178), • [MeasuredValue] Master (Bundle identifier) (SR0140.8.10) process parameter (GID-2671180), • [String] Master (Bundle identifier) (SR0140.8.11) process parameter (GID-2671182)

Step	#	Description
		▪ [Timestamp] Master (Bundle identifier) (SR0140.8.12) process parameter (GID-2671184), already exist, phase creates the **Context and key check (SR0140.3.2.1)** system-triggered exception (GID-2671185). Otherwise continue with step 60.
System writes context data	60	Phase stores the context data with the context identifier defined by the **Context definition (SR0140.8.3)** process parameter (GID-2671168)and key and value defined at any of the bundle process parameters ▪ [BigDecimal] Master (Bundle identifier) (SR0140.8.6) process parameter (GID-2671172), ▪ [Boolean] Master (Bundle identifier) (SR0140.8.7) process parameter (GID-2671174), ▪ [Duration] Master (Bundle identifier) (SR0140.8.8) process parameter (GID-2671176), ▪ [Long] Master (Bundle identifier) (SR0140.8.9) process parameter (GID-2671178), ▪ [MeasuredValue] Master (Bundle identifier) (SR0140.8.10) process parameter (GID-2671180), ▪ [String] Master (Bundle identifier) (SR0140.8.11) process parameter (GID-2671182), ▪ [Timestamp] Master (Bundle identifier) (SR0140.8.12) process parameter (GID-2671184), in the database.
	70	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3 Process Parameters (SR0140.8+)

The following process parameters define the behavior of the phase.

8.3.1 Instruction Table-specific Parameters

8.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

8.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

8.3.2 Instruction Link-specific Parameters

8.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671165). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

8.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system. Maximum length is 256 characters.

8.3.3 Basic Parameters

8.3.3.1 GID-2671166 INSTRUCTION (SR0140.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.3.2 GID-2671167 MODE (SR0140.8.2)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Manual completion** (default): Operator confirms the phase. **Automatic completion**: Phase is automatically completed after the data has been written.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.3.3 GID-2671168 CONTEXT DEFINITION (SR0140.8.3)

Attribute	Type	Comment
Identifier	String	Defines the context identifier for all key/value pairs. Maximum length is 250 characters.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.4 Configuration of System-triggered Exceptions

8.3.4.1 GID-2671169 CONTEXT AND KEY CHECK (SR0140.8.5)

Attribute	Type	Comment
Enabled	String	Controls if a check is performed.
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Context and key check (SR0140.3.2.1)** system-triggered exception (GID-2671185).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.5 Configuration of User-triggered Exceptions

8.3.5.1 GID-2671170 OVERRIDE VALUE (SR0140.8.4)

Attribute	Type	Comment
Risk assessment	Choice list	Defines the risk level of the exception and thus controls the related signature privilege. Available settings: **None**, **Low**, **Low (mandatory comment)**, **Medium**, **Medium (mandatory comment)**, **High**, **High (mandatory comment)**. Default setting: **High**.

Attribute	Type	Comment
Exception text	Text	Defines the exception description used during exception handling and within the batch record. Maximum length is 250 characters.

See also **Override value (SR0140.3.1.1)** user-triggered exception (GID-2671187).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.6 BigDecimal Value Bundle

8.3.6.1 [BigDecimal] Bundle process parameters (Framework capability)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2].

8.3.6.2 GID-2671172 [BigDecimal] Master (Bundle identifier) (SR0140.8.6)

Attribute	Type	Comment
Key	String	Defines the key that can be used with the context identifier to retrieve the value. Maximum length is 250 characters.
Value	BigDecimal	Defines the value for the key and context identifier.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.7 Boolean Value Bundle

8.3.7.1 [BOOLEAN] BUNDLE PROCESS PARAMETERS ()

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2].

8.3.7.2 GID-2671174 [BOOLEAN] MASTER (BUNDLE IDENTIFIER) (SR0140.8.7)

Attribute	Type	Comment
Key	String	Defines the key that can be used with the context identifier to retrieve the value. Maximum length is 250 characters.
Value	Boolean	Defines the value for the key and context identifier.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.8 Duration Value Bundle

8.3.8.1 [DURATION] BUNDLE PROCESS PARAMETERS ()

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2].

8.3.8.2 GID-2671176 [DURATION] MASTER (BUNDLE IDENTIFIER) (SR0140.8.8)

Attribute	Type	Comment
Key	String	Defines the key that can be used with the context identifier to retrieve the value. Maximum length is 250 characters.
Value	Duration	Defines the value for the key and context identifier.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.9 Long Value Bundle

8.3.9.1 [LONG] BUNDLE PROCESS PARAMETERS ()

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2].

8.3.9.2 GID-2671178 [LONG] MASTER (BUNDLE IDENTIFIER) (SR0140.8.9)

Attribute	Type	Comment
Key	String	Defines the key that can be used with the context identifier to retrieve the value. Maximum length is 250 characters.
Value	Long	Defines the value for the key and context identifier.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.10 Measured Value Bundle

8.3.10.1 [MEASURED VALUE] BUNDLE PROCESS PARAMETERS ()

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2].

8.3.10.2 GID-2671180 [MEASURED VALUE] MASTER (BUNDLE IDENTIFIER) (SR0140.8.10)

Attribute	Type	Comment
Key	String	Defines the key that can be used with the context identifier to retrieve the value. Maximum length is 250 characters.
Value	MeasuredValue	Defines the value for the key and context identifier.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.11 String Value Bundle

8.3.11.1 [STRING] BUNDLE PROCESS PARAMETERS (FRAMEWORK CAPABILITY)

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2].

8.3.11.2 GID-2671182 [STRING] MASTER (BUNDLE IDENTIFIER) (SR0140.8.11)

Attribute	Type	Comment
Key	String	Defines the key that can be used with the context identifier to retrieve the value. Maximum length is 250 characters.
Value	String	Defines the value for the key and context identifier.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.3.12 Timestamp Value Bundle

8.3.12.1 [TIMESTAMP] BUNDLE PROCESS PARAMETERS ()

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2].

8.3.12.2 GID-2671184 [TIMESTAMP] MASTER (BUNDLE IDENTIFIER) (SR0140.8.12)

Attribute	Type	Comment
Key	String	Defines the key that can be used with the context identifier to retrieve the value. Maximum length is 250 characters.
Value	Timestamp	Defines the value for the key and context identifier.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.4 Exceptions (SR0140.3+)

The phase supports user-defined, user-triggered (GID-2669379), system-triggered (GID-2669378), and post-completion exceptions (GID-2669380)and their configuration by means of process parameters (GID-2667961).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

8.4.1 System-triggered Exceptions (SR0140.3.2+)

A system-triggered exception is represented in a message dialog along with an **Exception** button, in the Exception Window as the read-only description of the exception, and in the batch report.

The following system-triggered exceptions are available.

8.4.1.1 GID-2671185 CONTEXT AND KEY CHECK (SR0140.3.2.1)

If enabled, the **Context and key check** exception checks if for the context identifier and key there is already a data set, which would consequently be updated.

Representation of the exception:

- \<Exception text>
  (taken from **Context and key check (SR0140.8.5)** process parameter (GID-2671169))
  The \<Key> key already exists and will be updated.

  - Example:
    Unexpected update of existing key, review of recipe is needed.
    The washing program key already exists and will be updated.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.1.2 GID-2671186 CONTEXT AND KEY CHECK LOGIC (SR0140.3.2.1.1)

- Trigger: Operator confirms phase

- Postcondition: Exception is recorded

Step	#	Description
Operator confirms phase	10	Phase creates **Context and key check (SR0140.3.2.1)** system-triggered exception.

Step	#	Description
Operator triggers and confirms exception	20	Phase records the exception and returns to the **Active mode (SR0140.1.2) layout** (GID-2671152).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.2 User-triggered Exceptions (SR0140.3.1+)

A user-triggered exception is represented in the list of available user-triggered exceptions in the Exception Window, as the description of the exception, and in the batch report.

The following user-triggered exceptions are available.

8.4.2.1 GID-2671187 OVERRIDE VALUE (SR0140.3.1.1)

The **Override value** exception allows an operator to change the value for a bundle parameter that was defined in the master recipe or master workflow. Each defined bundle parameter allows a data type-specific change of the value.

Representation during exception handling:

- Instruction
  <bundle parameter key>
  Override the defined value:
  Current value <current value>
  Override value <box for a new value, in case of a boolean value bundle display options (Yes, No)>
  Confirm button.

- Exception text:
  <Exception text>
  (taken from **Override value (SR0140.8.4)** process parameter (GID-2671170))
  Manual override of value for the <bundle parameter key> key.
  Old value: <Old value>
  New value: <New value>

  - Example:
    Review of recipe definitions required.
    Manual override of value for the washing program key.
    Old value: CleanP102
    New value: CleanP109

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.2.2 GID-2671188 OVERRIDE VALUE - LOGIC (SR0140.3.1.1.1)

- Trigger: Exception is selected

- Postcondition: Changed value is available

Step	#	Description
Operator confirms exception	10	Phase checks the format of the input. In case of an input with wrong format, the phase shows an error message. Depending on the type of the bundle parameter, the following error messages are displayed: • **Override BigDecimal value with wrong format (SR0140.3.6.4)** error (GID-2669384) • **Override Duration value with wrong format (SR0140.3.6.5)** error (GID-2669385) • **Override Long value with wrong format (SR0140.3.6.6)** error (GID-2669386) • **Override Measured Value with wrong format (SR0140.3.6.7)** error (GID-2669387) • **Override Timestamp value with wrong format (SR0140.3.6.8)** error (GID-2669388) If no error has occurred, phase shows the exception description to be signed according to the **Override value (SR0140.8.4)** process parameter (GID-2671170).
Operator signs exception	20	Phase records the exception and updates the value for key and context identifier to be used.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

8.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

8.5 Information Messages

There are no information messages available.

8.6 Questions

There are no questions available.

8.7 Decisions

There are no decisions available.

8.8 Error Messages (SR0140.3.6+)

Error messages are represented in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

8.8.1 GID-2669381 Key not defined (SR0140.3.6.1)

UI text	Comment
<Information that a key is not defined for a bundle parameter.>	Message pack: PhaseWriteContextData<version> Message ID: ContextDataKeyEmptyException_msg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.8.2 GID-2669382 Context identifier not defined (SR0140.3.6.2)

UI text	Comment
<Information that context identifier is not defined.>	Message pack: PhaseWriteContextData<version> Message ID: ContextIdentifierEmptyException_msg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.8.3 GID-2669383 Change of data type not allowed (SR0140.3.6.3)

UI text	Comment
<Information that an existing key exists with different data type. Change of data type is not allowed.>	Message pack: PhaseWriteContextData<version> Message ID: ContextDataExistsWrongDataTypeException_msg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.8.4 GID-2669384 Override BigDecimal value with wrong format (SR0140.3.6.4)

UI text	Comment
<Information that the override value has a wrong format.>	Message pack: PhaseWriteContextData<version> Message ID: OverrideBigDecimalValueError_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.8.5 GID-2669385 Override Duration value with wrong format (SR0140.3.6.5)

UI text	Comment
<Information that the override value has a wrong format.>	Message pack: PhaseWriteContextData<version> Message ID: OverrideDurationValueError_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.8.6 GID-2669386 Override Long value with wrong format (SR0140.3.6.6)

UI text	Comment
<Information that the override value has a wrong format.>	Message pack: PhaseWriteContextDataversion> Message ID: OverrideLongValueError_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.8.7 GID-2669387 Override Measured Value with wrong format (SR0140.3.6.7)

UI text	Comment
<Information that the override value has a wrong format.>	Message pack: PhaseWriteContextData<version> Message ID: OverrideMeasuredValueValueError_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.8.8 GID-2669388 Override Timestamp Value with wrong format (SR0140.3.6.8)

UI text	Comment
<Information that the override value has a wrong format.>	Message pack: PhaseWriteContextData<version> Message ID: OverrideTimestampValueError_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

8.9   Output Variables (SR0140.9+)

The following output variables are available to reference the phase's output.

8.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

8.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

8.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

8.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

8.9.5 GID-3077368 Context identifier (SR0140.9.1)

- Data type: String

- Usage: The output variable provides the context identifier that was used to store the keys and values and is taken from the **Context definition (SR0140.8.3)** process parameter (GID-2671168).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9 Send User Notification Phase (SR0150+)

The **Send user notification** phase allows to inform an operator on the shop floor about important data that is required to complete the current process in time and with the appropriate priority or to support the operator with taking the right decisions.

Example use cases are:
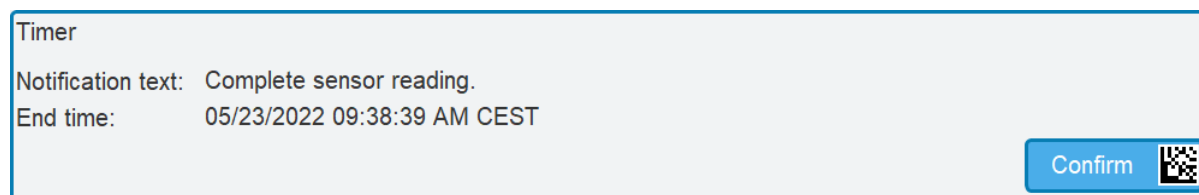
- Send a timestamp to a filling operation to display a countdown timer by which the material must be used and the filling process stopped.

- Send a timestamp by which the cleaning process will be finished.

Each recorded value is stored in the batch record, thereby becoming available for documentation purposes in the sub-report and batch report (GID-2669396).

Anomalies that occur during processing are covered by the phase exception handling (GID-2668212) (e.g., missing timestamp data).

After completion, the phase displays the notification text that will be displayed in the notification panel of the target Production Execution Client and the bundle type-specific value sent with the notification.

The Navigator displays the bundle type-specific value of the notification.

Timer	
Notification text:	Complete sensor reading.
End time:	05/23/2022 09:38:39 AM CEST
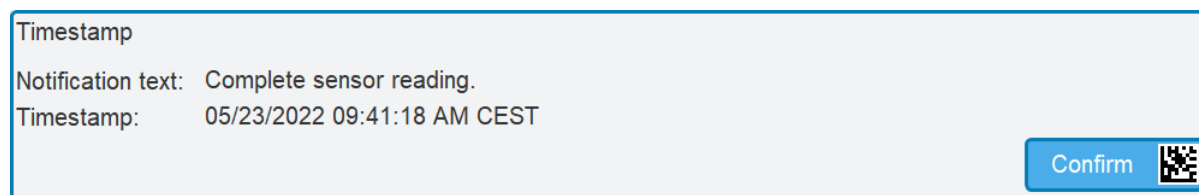
Figure 11: Send user notification during execution - Timer notification

Timestamp	
Notification text:	Complete sensor reading.
Timestamp:	05/23/2022 09:41:18 AM CEST

Figure 12: Send user notification during execution - Timer notification

9.1 Layout

The phase provides individual layouts for its representation during execution (GID-2669394), in the Navigator (GID-2669395), and in the sub-report (GID-2669396)

9.1.1 Representation during Execution (SR0150.1+)

The representation during execution depends on the phase mode.

9.1.1.1 GID-2671189 PREVIEW MODE (SR0150.1.1)

1. <Instruction text>
   (taken from **Instruction (SR0150.8.1)** process parameter (GID-2671204)).

2. Notification text (as defined by the **Notification Configuration (SR0150.8.3)** process parameter (GID-2671206)).

3. Notification timestamp (as defined by the **Timer notification - End time (SR0150.8.4)** process parameter (GID-2671207)or the **Timestamp notification - Timestamp** (SR0150.8.5) process parameter (GID-2671208).

4. **Confirm** button (disabled).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

9.1.1.2 GID-2671190 ACTIVE MODE (SR0150.1.2)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase).

2. <Instruction text>
   (taken from **Instruction (SR0150.8.1)** process parameter (GID-2671204)).

3. Notification text (as defined by the **Notification Configuration (SR0150.8.3)** process parameter (GID-2671206).

4. Notification timestamp (as defined by the **Timer notification - End time (SR0150.8.4)** process parameter (GID-2671207)or the **Timestamp notification - Timestamp** (SR0150.8.5) process parameter (GID-2671208).

5. **Confirm** button.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.1.1.3 GID-2671191 COMPLETED MODE (SR0150.1.3)

1. Instruction table panel and/or instruction link panel
   (only if an instruction table and/or instruction link is defined for the phase).

2. <Instruction text>
   (taken from **Instruction (SR0150.8.1)** process parameter (GID-2671204)).

3. Notification text (as defined by the **Notification Configuration (SR0150.8.3)** process parameter (GID-2671206)

4. Notification timestamp (as defined by the **Timer notification - End time (SR0150.8.4)** process parameter (GID-2671207) the **Timestamp notification - Timestamp** (SR0150.8.5) process parameter (GID-2671208)..

5. **Confirm** button (completed).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.1.2 Representation in Navigator (SR0150.4+)

The Navigator provides the following details:

9.1.2.1 PHASE COLUMN (FRAMEWORK CAPABILITY)

- <Phase name>

  - Example:
    Send filling end.

9.1.2.2 GID-2671193 INFORMATION COLUMN (SR0150.4.1)

- Notification timestamp (as defined by the **Timer notification - End time (SR0150.8.4)** process parameter (GID-2671207)or the **Timestamp notification - Timestamp** (SR0150.8.5) process parameter (GID-2671208).

- Example: 5/Sep/2021 19:26:35 CET

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

9.1.2.3 ACTION COLUMN

- There are no phase-specific actions available.

9.1.3 Representation in Sub-report (SR0150.5+)

The sub-report contains the following information:

9.1.3.1 COMMON SUB-REPORT ELEMENTS (FRAMEWORK CAPABILITY)

- <Start time>

- <Completion time>

- <Unit procedure> / <operation> / <phase>

- <Work center> / <station> / <device> - <phase completion user>

9.1.3.2 GID-2671196 SUB-REPORT ELEMENTS (SR0150.5.1)

- Instruction table panel and/or instruction link panel
  (only if an instruction table and/or instruction link is defined for the phase)

- Instruction text

- Reference path

- Notification text

- Notification end time or Timestamp (depends on used notification bundle parameter)

- Alarm

- Pinned

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.2 Business Logic (SR0150.2+)

The phase implements the following business logic.

9.2.1 Phase Mode

Business logic related to phase modes.

9.2.1.1 GID-2671197 MANUAL COMPLETION MODE (SR0150.2.1)

- Function: **Manual completion** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is active

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0150.1.2)** layout (GID-2671190).
	20	In case there is an incomplete phase configuration the phase displays the **Phase configuration incomplete (SR0150.3.6.1)** error message text (GID-2669406) as part of the phase view.
Phase completion	30	See **Confirm phase (SR0150.2.3)** function (GID-2671199).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.2.1.2 GID-2671198 AUTOMATIC COMPLETION MODE (SR0150.2.2)

- Function: **Automatic completion** mode of phase

- Type: Phase mode

- Trigger: Phase becomes active

- Postcondition: Phase is completed

Step	#	Description
Phase activation	10	Phase displays its user interface according to the **Active mode (SR0150.1.2)** layout (GID-2671190).
	20	In case there is an incomplete phase configuration the phase displays the **Phase configuration incomplete (SR0150.3.6.1)** error message text (GID-2669406)as part of the phase view.
	30	The system tries to confirm the phase immediately as if the operator had used the **Confirm** button of the phase to trigger the **Confirm phase (SR0150.2.3)** function (GID-2671199).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

9.2.2 Main Path

Business logic related to the main path:

9.2.2.1 GID-2671199 CONFIRM PHASE (SR0150.2.3)

Function: Completion of phase

Trigger: Operator confirms phase

Postcondition: Phase is completed

Step	#	Description
Operator confirms phase	10	Operator confirms that the notification shall be sent.
Check configuration errors	12	If the phase already displays incomplete phase configuration information, it cannot be completed and displays the **Phase configuration incomplete (SR0150.3.6.1)** error message (GID-2669406).
System builds the notification	20	The notification identifier is copied from the **Notification Bundle Configuration (SR0150.8.3)** process parameter (GID-2671206). If it is empty, a unique value will be generated. The path of the notification is built as concatenation of the current order or workflow identifier and the reference path of the **Notification Bundle Configuration (SR0150.8.3)** process parameter (GID-2671206). The notification text is copied from the **Notification Bundle Configuration (SR0150.8.3)** process parameter link.
System extends the notification bundle type specifically	30	[Timer] Bundle: ▪ As value, the timestamp defined by the **End Time (SR0150.8.4)** process parameter (GID-2671207)is used. ▪ The notification will not be displayed as an alarm. ▪ The notification will be pinned. [Timestamp] Bundle: ▪ As value, the timestamp defined by the **Timestamp (SR0150.8.5)** process parameter (GID-2671208)is used. ▪ The notification will be displayed as an alarm if the **Alarm (SR0150.8.6)** process parameter (GID-2671209)is enabled. ▪ The notification will be pinned if the **Pinned (SR0150.8.7)** process parameter (GID-2671210)is enabled.

Step	#	Description
Check for notification update	35	System checks if there already exists a notification with the same notification identifier for the current order or workflow. ▪ If not: system proceeds with step 40. ▪ If yes: system checks if the current notification has the same notification type and reference path as the existing one. If yes, the system proceeds with step 40, which will result in a notification update. If not, the system proceeds with step 50.
	40	System sends the notification.
	50	Phase is completed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.3   Process Parameters (SR0150.8+)

The following process parameters define the behavior of the phase.

9.3.1   Instruction Table-specific Parameters

9.3.1.1 INSTRUCTION TABLE DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Table layout	Choice list	Defines the layout of the instruction table holding the instruction texts. Available settings: **1 column**, **2 columns**, **3 columns**, **4 columns**, **5 columns**. Default setting: **1 column**.
First column narrow	Boolean	Defines if the first column of the table shall be narrow.
Show all borders	Boolean	Defines if the borders of the table shall be visible.

9.3.1.2 INSTRUCTION TABLE TEXT (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Column 1	HTML text	Instruction text to be displayed in a column. **Restriction**: Maximum length is 2000 characters (including HTML tags).
Column 2	HTML text	
Column 3	HTML text	
Column 4	HTML text	
Column 5	HTML text	

9.3.2 Instruction Link-specific Parameters

9.3.2.1 INSTRUCTION TEXT WITH LINKS (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Instruction text	HTML text	Instruction text to be displayed. For any text enclosed in curly brackets you can define a hyperlink with the **Instruction link definition** process parameter (GID-2671203). Example: Refer to {SOP1270} for guidance. Maximum length is 2000 characters (including HTML tags).

9.3.2.2 INSTRUCTION LINK DEFINITION (FRAMEWORK CAPABILITY)

Attribute	Type	Comment
Link text	Text	Text to be used as link. For any text enclosed in curly brackets within the instruction text you can define a link with the **Link URL** attribute. Including the brackets in the link text is optional. Maximum length is 80 characters.

Attribute	Type	Comment
Link URL	Text	URL of the file to be displayed. The link opens the external application assigned to the file type by the operating system.

Maximum length is 256 characters. |

9.3.3 Basic Parameters

9.3.3.1 GID-2671204 INSTRUCTION (SR0150.8.1)

Attribute	Type	Comment
Text	HTML text	Instruction text to be displayed. **Restriction**: Maximum length is 4000 characters (including HTML tags).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.3.2 GID-2671205 MODE (SR0150.8.2)

Attribute	Type	Comment
Mode	Choice list	Defines the processing mode. **Manual completion** (default): Operator confirms the phase. **Automatic completion**: Phase is automatically completed after the data has been written.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.4 *Notification Bundle Parameters*

Independent of the notification type, a **Notification Bundle Configuration (SR0150.8.3)** process parameter (GID-2671206)is part of the definition.

For the master process parameter of a bundle, its internal identifier is populated from the bundle identifier.

For all other process parameters of the bundle, their internal identifier is a concatenation of the bundle identifier and the process parameter name.

This framework capability refers to **Bundle Process Parameters (SR3146.9.7.4.1)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667978).

9.3.4.1 GID-2671206 NOTIFICATION CONFIGURATION (SR0150.8.3)

Only one notification bundle parameter can be defined.

Attribute	Type	Comment
Notification identifier	String	Together with the order or workflow identifier, it represents a unique value and can be used to update the notification text and/or value of the same bundle type within a further notification. Maximum length is 80 characters.
Reference path	String	Defines the visibility of the notification. Allowed values are ▪ Empty ▪ Unit procedure ▪ Unit procedure / Operation Can be defined with the **Unit Procedure and Operation Path Editor (SR3146.9.2.17.5)** (for details, see **Other Editors (SR3146.9.2.17)** in "Functional Requirement Specification Recipe and Workflow Management" [A2]). Maximum length is 1024 characters. **TIP** A notification update needs to use the same reference path and notification type as the initial notification.

Attribute	Type	Comment
Notification text	String	Defines the text to be displayed in the target Production Execution Client in the first column of the notification panel. Maximum length is 1024 characters. **TIP** HTML tags will be shown as plain text and not interpreted by the notification panel.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.4.2 GID-2671207 TIMER NOTIFICATION - END TIME (SR0150.8.4)

Attribute	Type	Comment
Timestamp	Timestamp	Defines the timestamp by which the countdown timer must reach 0. Can be defined with a Date/Time Picker editor or an expression.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.4.3 GID-2671208 TIMESTAMP NOTIFICATION - TIMESTAMP (SR0150.8.5)

Attribute	Type	Comment
Timestamp	Timestamp	Defines the timestamp to be displayed with the notification. Can be defined with a Date/Time Picker editor or an expression.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.4.4 GID-2671209 TIMESTAMP NOTIFICATION - ALARM (SR0150.8.6)

Attribute	Type	Comment
Enabled	Boolean	Defines whether the notification will be displayed as an alarm or not. Default setting: **No.**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.4.5 GID-2671210 TIMESTAMP NOTIFICATION - PINNED (SR0150.8.7)

Attribute	Type	Comment
Enabled	Boolean	Defines whether the notification will be pinned at the top of the notification panel list or not. Default setting: **No.**

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.4 Exceptions (SR0150.3+)

The phase supports user-defined, user-triggered (GID-2669404)), system-triggered (GID-2669403), and post-completion exceptions (GID-2669405)and their configuration by means of process parameters (GID-2668211).

User-defined exceptions cannot be configured by process parameters since they are provided by the framework and independent of phases.

9.4.1 System-triggered Exceptions

There are no system-triggered exceptions available.

9.4.2 User-triggered Exceptions

There are no user-triggered exceptions available.

9.4.3 Post-completion Exceptions

There are no post-completion exceptions available.

9.5 Information Messages

There are no information messages available.

9.6 Questions

There are no questions available.

9.7 Decisions

There are no decisions available.

9.8 Error Messages (SR0150.3.6+)

Error messages are represented as part of the phase view or in an error message dialog containing a message type-specific icon, the error message, and an **OK** button.

The following error messages are available to inform the operator about error conditions.

9.8.1 GID-2669406 Phase configuration incomplete (SR0150.3.6.1)

UI text	Comment
A configuration error has occurred.	Message pack: PhaseSendUserNotif<version> Message ID: wrongConfiguration_ErrorMsg
There is no parameter bundle defined.	Message pack: PhaseSendUserNotif<version> Message ID: noBundles_ErrorMsg
There is no end time defined.	Message pack: PhaseSendUserNotif<version> Message ID: endTimeNotSet_ErrorMsg
There is no timestamp defined.	Message pack: PhaseSendUserNotif<version> Message ID: timestampNotSet_ErrorMsg
Please abort the phase.	Message pack: PhaseSendUserNotif<version> Message ID: startAbort_ErrorMsg
Please use the Repair function to correct the issue or abort the phase.	Message pack: PhaseSendUserNotif<version> Message ID: startRepairOrAbort_ErrorMsg

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.9 Output Variables (SR0150.9+)

The following output variables are available to reference the phase's output.

9.9.1 Instance count (Framework capability)

- Data type: Long

- Usage: The output variable provides the count of the number of instances the phase has been processed, for example in a loop. The count is also increased when the phase is skipped from an operator's perspective, since the phase is still executed, but as a hidden phase.
  The count variable of a phase that has not been executed provides 0 as output value.

9.9.2 Start time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the start time of the phase.

9.9.3 Completion time (Framework capability)

- Data type: Timestamp

- Usage: The output variable provides the completion time of the phase.

9.9.4 Identifier (Framework capability)

- Data type: String

- Usage: The output variable provides the identifier of the phase.

9.9.5 GID-2669411 User notification identifier (SR0150.9.1)

- Data type: String

- Usage: The output variable provides the identifier that was sent with the notification. It can be used to update the notification.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.9.6 Notification Bundle

Bundle output variable (Framework capability)

For all output variables of the same bundle, the output variable identifier is a concatenation of the bundle identifier and the output variable name.

This framework capability refers to **Bundle Output Variable (SR3146.9.7.4.2)** in "Functional Requirement Specification Recipe and Workflow Management" [A2] (GID-2667978).

9.9.6.1 GID-2671211 [TIMER NOTIFICATION] END TIME (SR0150.9.2)

- Data type: Timestamp

- Usage: The output variable provides the defined value of the countdown timer end time.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.9.6.2 GID-2671212 [TIMER NOTIFICATION] TIMESTAMP (SR0150.9.3)

- Data type: Timestamp

- Usage: The output variable provides the defined timestamp value.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

10 Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	FT PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM007B-EN-E
A2	FT PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM011B-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

11 Document Information

The document information covers various data related to the document.

11.1 Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Norbert Ern	Product Owner
Jürgen Stieber	Technical Lead
Ignaz Wangler	Test Lead

11.2 Version Information

Object	Version
FT PharmaSuite	11.01.00
Show Instruction Text	11.0
Show Document	11.1
Upload Image	11.0
Upload PDF	11.0
Show URL	11.0
Create Workflow	11.0
Write Context Data	11.0
Send User Notification	11.0
Functional Requirement Specification	1.0

FT PharmaSuite® 11.01.00 - Functional Requirement Specification EBR Phases

12 Appendix A - Revision History

12.1 Updated Requirements

GID-2670999 Instruction (SR0030.8.1)

GID-2667916 Show Document (SR0040+)

GID-2671001 Preview mode (SR0040.1.2)

GID-2671002 Active mode (SR0040.1.1)

GID-2671003 Completed mode (SR0040.1.3)

GID-2671008 Sub-report elements (SR0040.5.1)

GID-2671013 Instruction (SR0040.8.1)

GID-2671014 Document (SR0040.8.2)

GID-2671055 Load image (SR0090.2.5)

GID-2671061 Instruction (SR0090.8.1)

GID-2669293 Maximum file size (SR0090.11.1)

GID-2671083 Automatic loading mode (SR0100.2.6)

GID-2671084 Automatic completion mode (SR0100.2.7)

GID-2671086 Load PDF (SR0100.2.5)

GID-2671092 Instruction (SR0100.8.1)

GID-2671116 Instruction (SR0120.8.1)

GID-2671138 Instruction (SR0130.8.1)

GID-2671152 Active mode (SR0140.1.2)

GID-2671166 Instruction (SR0140.8.1)

GID-2671204 Instruction (SR0150.8.1)

12.2 Added Requirements

None

12.3 Deleted Requirements

None

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